

US3512036 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:58:39

All time stamps listed in this document are displayed in GMT

US3512036

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 20:29:16

Generated On: 10 Jun 2021 07:58:39

[Participant ID](#)

US3512036

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

US3512036

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3512036

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female <input type="radio"/> Male <input checked="" 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

US3512036

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input 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

US3512036

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3512036

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Were any significant conditions reported?

Yes ☒

No ☐

US3512036

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	RAGWEED ALLERGY
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	NEARSIGHTED BILATERAL
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	PERFORATED LEFT EARDRUM
Start date (dd MMM yyyy)	UN UNK 1991
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3512036

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	LEFT EAR TINNITUS
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512036

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	ACNE FACE AND BACK
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3512036

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	FOLLICULITIS OF FACE
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3512036

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	OSTEOARTHRITIS OF THE NECK
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	GOUT BILATERAL FEET
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)	_____

US3512036

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	THYROID CANCER
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3512036

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512036

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	ATRIAL FIBRILLATION
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)	_____

US3512036

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	POOR CIRCULATION IN BILATERAL LEGS
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)	

US3512036

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	SWELLING IN BILATERAL LEGS AND FEET
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)	

US3512036

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	C. DIFF INFECTION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3512036

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	TETAROLOGY OF FALLOUT
Start date (dd MMM yyyy)	(b) (6) 1976
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 1978
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1976
Start Year (derived)	1976
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

US3512036

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	TETAROLOGY OF FALLOUT REPAIR
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

US3512036

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	DEVIATED SEPTUM
Start date (dd MMM yyyy)	(b) (6) 1976
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)	(b) (6) 1976
Start Year (derived)	1976
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512036

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	SINUS SURGERY DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

US3512036

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	SINUS SURGERY DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

US3512036

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	SINUS SURGERY DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3512036

Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	PERFORATED LEFT EARDRUM REPAIR
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

US3512036

Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	THYROIDECTOMY
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

US3512036

Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	L4-L5 DISCECTOMY
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3512036

Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (35)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

Condition	OSTEOARTHRITIS LOWER BACK
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3512036

Folder: Screening

Form: Medical History (36)

Data signed: (b) (4) 26 Mar 2021 18:33:19

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:26 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 08:26
Height (<i>xxx.x</i>)	76 in
Weight (<i>xxx.x</i>)	261.2 lb
BMI (<i>xxx.x</i>)	31.86074 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)	

US3512036

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3512036

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

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

(b) (6)

INFORMATION
TECHNOLOGY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3512036

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3512036

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 143004

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 ☒

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Height	ND - Not Done
Weight	ND - Not Done

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

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)	12 AUG 2020
Time of assessment (00:00-23:59)	08:26 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 08:26
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

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)	12 AUG 2020
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 10:31
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3512036

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

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.

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 10:01 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 10:01

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

US3512036

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 AUG 2020
Collection time (00:00-23:59)	09:07 (24 HR)
Collection date and time (derived)	12 AUG 2020 09:07

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:00	12 AUG 2020 09:00
Nasopharyngeal Swab 2	No		

US3512036

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

12 AUG 2020 10:39

PC Open Date & Time

12 AUG 2020 10:21

PC Close Date & Time

12 AUG 2020 12:51

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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 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	13 AUG 2020 07:42
PC Open Date & Time	12 AUG 2020 13:46
PC Close Date & Time	13 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

13 AUG 2020 18:02

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 22:46

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

98.8 °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

15 AUG 2020 20:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

16 AUG 2020 21:29

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

17 AUG 2020 20:26

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 10:42

PC Open Date & Time

12 AUG 2020 10:21

PC Close Date & Time

12 AUG 2020 12:51

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

13 AUG 2020 07:42

PC Open Date & Time

12 AUG 2020 13:46

PC Close Date & Time

13 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

13 AUG 2020 18:00

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

14 AUG 2020 22:47

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

15 AUG 2020 20:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

16 AUG 2020 21:29

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

17 AUG 2020 20:26

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

18 AUG 2020 18:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 10:42
PC Open Date & Time	12 AUG 2020 10:21
PC Close Date & Time	12 AUG 2020 12:51

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 07:43
PC Open Date & Time	12 AUG 2020 13:46
PC Close Date & Time	13 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

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)

77 of 2636

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:01
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

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 ☒

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 22:47
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

81 of 2636

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:10
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

83 of 2636

EAB) (1725)

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 21:29
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

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)

85 of 2636

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:27
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

87 of 2636

EAB) (1725)

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:56
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3512036

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

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)	9 SEP 2020
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 08:48
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

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)	9 SEP 2020
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 10:22
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3512036

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

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.

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 09:51 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 09:51

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

US3512036

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	9 SEP 2020 09:30

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:08	9 SEP 2020 09:08
Nasopharyngeal Swab 2	No		

US3512036

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 10:24

PC Open Date & Time

09 SEP 2020 10:11

PC Close Date & Time

09 SEP 2020 12:41

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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 98.3 °F

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

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

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

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

PC Time Stamp 09 SEP 2020 20:14

PC Open Date & Time 09 SEP 2020 13:36

PC Close Date & Time 10 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	10 SEP 2020 21:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

11 SEP 2020 21:07

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

13 SEP 2020 12:52

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

15 SEP 2020 06:34

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

98.7 °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

15 SEP 2020 22:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

09 SEP 2020 10:24

PC Open Date & Time

09 SEP 2020 10:11

PC Close Date & Time

09 SEP 2020 12:41

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

09 SEP 2020 20:13

PC Open Date & Time

09 SEP 2020 13:36

PC Close Date & Time

10 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

10 SEP 2020 21:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

11 SEP 2020 21:07

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

13 SEP 2020 12:52

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

15 SEP 2020 06:34

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

15 SEP 2020 22:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 10:24
PC Open Date & Time	09 SEP 2020 10:11
PC Close Date & Time	09 SEP 2020 12:41

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 20:13
PC Open Date & Time	09 SEP 2020 13:36
PC Close Date & Time	10 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

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 ☒

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

125 of 2636

EAB) (1725)

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 21:08
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

127 of 2636

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

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)

129 of 2636

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:52
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

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)

131 of 2636

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:34
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

133 of 2636

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3512036

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:26 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 08:26
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512036

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

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.

US3512036

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	08:36 (24 HR)
Collection date and time (derived)	7 OCT 2020 08:36

US3512036

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:14

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 17:44:07

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 12:05:53

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 00:41:18

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 00:01:57

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 00:50:04

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

23 NOV 2020 07:16:34

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 01:48:06

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

19 DEC 2020 10:25:23

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

25 DEC 2020 03:55:55

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

01 JAN 2021 00:03:02

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

08 JAN 2021 07:34:49

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

15 JAN 2021 01:30:26

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 13:54:07

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

29 JAN 2021 02:53:42

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

05 FEB 2021 07:35:42

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

12 FEB 2021 05:43:05

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 05:50:48

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

28 FEB 2021 12:08:54

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

05 MAR 2021 07:01:14

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

12 MAR 2021 04:16:43

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

26 MAR 2021 16:23:00

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

02 APR 2021 05:16:44

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

12 APR 2021 19:52:42

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 02:07:58

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Date and time of submission

23 APR 2021 04:33:38

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 17:27:27

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 425

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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°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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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°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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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°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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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°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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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"/>

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:58:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:09:06

US3512036

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 20:40:14

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:30:13

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 17:27:19

Generated On: 10 Jun 2021 07:58:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:27:19

Generated On: 10 Jun 2021 07:58:39

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) _____

US3512036

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 17:27:19

Generated On: 10 Jun 2021 07:58:39

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.

US3512036

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 17:27:19

Generated On: 10 Jun 2021 07:58:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

12:26 (24 HR)

Collection date and time (derived)

30 MAR 2021 12:26

US3512036

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 17:27:19

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 12:00:23

Generated On: 10 Jun 2021 07:58:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3512036

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512036

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3512036

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:58:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3512036

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

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

Visit date (dd MMM yyyy)	11 FEB 2021
--------------------------	-------------

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

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

US3512036

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 12:43:40

Generated On: 10 Jun 2021 07:58:39

Date of updated informed consent (*dd MMM yyyy*) 11 FEB 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*) 11 FEB 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 _____

US3512036

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:29:16

Generated On: 10 Jun 2021 07:58:39

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

Collection date (dd MMM yyyy)	11 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:29 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	11 FEB 2021 11:29
------------------------------------	-------------------

US3512036

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 20:29:16

Generated On: 10 Jun 2021 07:58:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00 - 23:59)	11:26
Collection Date and Time (derived)	11 FEB 2021 11:26

US3512036

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 20:29:16

Generated On: 10 Jun 2021 07:58:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

AEID	
Adverse event	LEFT SHOULDER NERVE IMPINGEMENT
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)	27 AUG 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"/>

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

AEID	USA-US065-2020-MRNA-1273-P30 1000005
Adverse event	VENOUS THROMBOSIS OF RIGHT LOWER EXTREMITY
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)	2 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 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 type="radio"/> Grade 4 <input checked="" 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)	11 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	13 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	357 of 2636

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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 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:	DEEP VEIN THROMBOSIS OF RIGHT LOWER EXTREMITY
Narrative	

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

SUBJECT EXPERIENCED RIGHT
KNEE PAIN AND CALF
SWELLING ON 02 DEC 2020.
SYMPTOMS GRADUALLY
BEGAN TO WORSEN AND
CONTINUE UP THE INNER
THIGH. SUBJECT WENT TO HIS
PRIMARY CARE PHYSICIAN ON
11 DEC 2020 WHEN HE NOTICED
PAIN AND SWELLING IN HIS
RIGHT LOWER EXTREMITY. HIS
PRIMARY CARE PHYSICIAN
DIAGNOSED HIM WITH A
POSSIBLE DEEP VEIN
THROMBOSIS AND SENT HIM
TO BAPTIST SOUTH ER.
SUBJECT WAS ADMITTED ON 11
DEC 2020 AND DISCHARGED 13
DEC 2020. HE WAS STARTED ON
ELIQUIS, BUT DOSAGE IS NOT
KNOWN AT THIS TIME.
RECORDS HAVE NOT YET BEEN
RECEIVED. PAIN AND
SWELLING STILL CONTINUE
UPON DISCHARGE AND
SUBJECT STATES HE WAS TOLD
THIS WOULD TAKE MONTHS
TO RESOLVE. NO
COVID-TESTING DONE IN
HOSPITAL PER PT.

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

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

AEID	
Adverse event	DIVERTICULOSIS OF SIGMOID COLON
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)	13 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2636

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2636

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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)	

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

AEID	
Adverse event	DEEP VEIN THROMBOSIS OF RIGHT LOWER EXTREMITY
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)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

AEID	
Adverse event	HYPOKALEMIA
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)	11 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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)

366 of 2636

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

AEID	
Adverse event	WORSENING ACID REFLUX
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)	27 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 20:29:16

Generated On: 10 Jun 2021 07:58:39

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

Yes ☒

No ☐

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

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 137

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)

373 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 2001	
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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication ARIPIRAZOLE

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT EXPLOSIVE
DISORDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT BILATERAL FEET

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)

377 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 2016	
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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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)

379 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 2012	
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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS NECK/BACK
PAIN/RESTLESS LEG
SYNDROME

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 2016
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 2012	
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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication CETIRIZINE HYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 800

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)

387 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication FLUTICASONE PROPIONATE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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)

389 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT SHOULDER NERVE
IMPINGEMENT

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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)	7 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)	10 SEP 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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication VENOUS THROMBOSIS OF
RIGHT LOWER EXTREMITY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication VENOUS THROMBOSIS OF
RIGHT LOWER EXTREMITY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input 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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication VENOUS THROMBOSIS OF
RIGHT LOWER EXTREMITY

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication VENOUS THROMBOSIS OF
RIGHT LOWER EXTREMITY

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

399 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 DEC 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"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication HEPARIN/DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication VENOUS THROMBOSIS OF
RIGHT LOWER EXTREMITY

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)

401 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

403 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 1500

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

405 of 2636

EAB) (1725)

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 12:00:22

Generated On: 10 Jun 2021 07:58:39

	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)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512036

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 20:29:16

Generated On: 10 Jun 2021 07:58:39

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3512036

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:58:39

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

US3512036

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:39

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 ☐

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

SAEID	USA-US065-2020-MRNA-1273-P301000005
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)	6

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

SAEID	USA-US065-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	17/DEC/2020 08:27
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

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

SAEID	USA-US065-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	23/DEC/2020 08:19
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

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

SAEID	USA-US065-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	28/DEC/2020 11:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

SAEID	USA-US065-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	20/JAN/2021 17:34
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

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

SAEID	USA-US065-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	22/JAN/2021 07:51
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

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Feb 2021 20:29:17

Generated On: 10 Jun 2021 07:58:39

SAEID	USA-US065-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	12/FEB/2021 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3512036 (Prod: Jacksonville Center for Clinical Research Center)

US3512036

Form: Participant Creation

Generated On: 10 Jun 2021 07:58:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'US3512036'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 12:34:39

US3512036

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:34:31

US3512036

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 12:34:40

US3512036

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Clinic (Clinic)'	Taylor Johnson (b) (4)	12 Aug 2020 14:34:31

US3512036

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'SCRN'	System	12 Aug 2020 14:34:31

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered (b) (6) 1976'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 12:34:41

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '43'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'YEARS'	System	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '43'	System	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Male (M)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'I'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:35:50

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Aug 2020'	System	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2020'	System	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Amendment 2 (2)' reason for change:	(b) (4)	
Data Entry Error	Taylor Johnson (b) (4)	12 Aug 2020 15:12:20
User entered 'Amendment 5 (5)'	(b) (4)	
	Taylor Johnson (b) (4)	12 Aug 2020 14:36:12
	(b) (4)	

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:12

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 12:34:40

US3512036

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'I'	System	12 Aug 2020 14:36:18

US3512036

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:18

US3512036

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:58:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:45:07

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Ragweed allergy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:48:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:48:13
Data point term sent to Coder	System	12 Aug 2020 18:47:36
User entered 'RAGWEED ALLERGY'	Allison Crain (b) (4)	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	(b) (4)	12 Aug 2020 18:47:38
User entered 'UN UNK 1977' reason for change: Data Entry Error	Allison Crain (b) (4)	12 Aug 2020 18:47:38
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	12 Aug 2020 18:47:14
User entered 'UN UNK 1976'	System	12 Aug 2020 18:47:14
	Allison Crain (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1977'	System	12 Aug 2020 18:47:38
User entered 'Jan 1976'	System	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1977'	System	12 Aug 2020 18:47:38
User entered '1976'	System	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:47:14

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:50:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:50:18
Data point term sent to Coder	System	12 Aug 2020 18:48:38
User entered 'SEASONAL ALLERGIES'	Allison Crain (b) (4)	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1986'	Allison Crain (b) (4)	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1986'	System	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1986'	System	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:48:15

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:50:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:50:19
Data point term sent to Coder	System	12 Aug 2020 18:49:41
User entered 'ACID REFLUX'	Allison Crain (b) (4)	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2010'	Allison Crain (b) (4)	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2010'	System	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2010'	System	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:48:41

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:50:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:50:19
Data point term sent to Coder	System	12 Aug 2020 18:49:41
User entered 'GASTRIC ULCER'	Allison Crain (b) (4)	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2012'	Allison Crain (b) (4)	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2012'	Allison Crain (b) (4)	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2012'	System	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2012'	System	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2012'	System	12 Aug 2020 18:49:15

US3512036

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2012'	System	12 Aug 2020 18:49:15

Condition

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Aug 2020 18:50:19
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	12 Aug 2020 18:49:42
User entered 'NEARSIGHTED'	Allison Crain (b) (4)	12 Aug 2020 18:49:40
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1988'	Allison Crain (b) (4)	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1988'	System	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1988'	System	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:49:40

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Middle ear disorders (excl congenital), HLT: Tympanic membrane disorders (excl infections), PT: Tympanic membrane perforation, LLT: Perforated eardrum - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 12:29:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 12:29:24
Data point term sent to Coder	System	12 Aug 2020 18:51:50
User entered 'PERFORATED LEFT EARDRUM'	Allison Crain (b) (4)	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1991' reason for change:	(b) (4)	
Data Entry Error	Brenda Anderson (b) (4)	07 Oct 2020 15:58:49
User entered 'UN UNK 1996'	(b) (4)	
	Allison Crain (b) (4)	12 Aug 2020 18:51:48
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of PERFORATED LEFT EARDRUM REPAIR was performed in UNK 1991. Please review and update if appropriate. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:26:20
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of PERFORATED LEFT EARDRUM REPAIR was performed in UNK 1991. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 16:35:57
User entered 'UN UNK 1996'	Allison Crain (b) (4)	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1991'	System	07 Oct 2020 15:58:49
User entered 'Jan 1996'	System	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1991'	System	07 Oct 2020 15:58:49
User entered '1996'	System	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1996'	System	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1996'	System	12 Aug 2020 18:51:48

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:59:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:59:17
Data point term sent to Coder	System	12 Aug 2020 18:58:05
User entered 'LEFT EAR TINNITUS'	Allison Crain (b) (4)	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1996'	Allison Crain (b) (4)	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1996'	System	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1996'	System	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:57:05

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:00:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:00:08
Data point term sent to Coder	System	12 Aug 2020 18:59:06
User entered 'SLEEP APNEA'	Allison Crain (b) (4)	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2002'	Allison Crain (b) (4)	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2002'	System	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2002'	System	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:58:18

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Per DM CLR: Please specify the location of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 09:38:14
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) (b) (4)	08 Oct 2020 23:14:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:14:27
Data point term sent to Coder	System	07 Oct 2020 15:54:55
Query 'Per DM CLR: Please specify the location of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 15:54:40
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 15:54:33
User entered 'ACNE face and back' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 15:54:33
User opened query 'Per DM CLR: Please specify the location of ACNE. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:57:53
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) (b) (4)	12 Aug 2020 19:00:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:00:09
Data point term sent to Coder	System	12 Aug 2020 18:59:07
User entered 'ACNE'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1988'	Allison Crain (b) (4)	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1999'	Allison Crain (b) (4)	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1988'	System	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1988'	System	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1999'	System	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1999'	System	12 Aug 2020 18:58:42

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Per DM CLR: Please specify the location of FOLLICULITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:38:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Folliculitis, LLT: Folliculitis - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 11:18:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 11:18:20
Data point term sent to Coder	System	07 Oct 2020 15:55:59
Query 'Per DM CLR: Please specify the location of FOLLICULITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4)	07 Oct 2020 15:55:39
Coding entries removed.	Brenda Anderson (b) (4)	07 Oct 2020 15:55:30
User entered 'FOLLICULITIS of face' reason for change: Data Entry Error	Brenda Anderson (b) (4)	07 Oct 2020 15:55:30
User opened query 'Per DM CLR: Please specify the location of FOLLICULITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:58:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Folliculitis, LLT: Folliculitis - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 19:00:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 19:00:07
Data point term sent to Coder	System	12 Aug 2020 18:59:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

541 of 2636

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
User entered 'FOLLICULITIS'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1988'	Allison Crain (b) (4)	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1999'	Allison Crain (b) (4)	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1988'	System	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1988'	System	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1999'	System	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1999'	System	12 Aug 2020 18:59:05

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of neck - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 12:39:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 12:39:21
Data point term sent to Coder	System	12 Aug 2020 19:00:10
User entered 'OSTEOARTHRITIS OF THE NECK'	Allison Crain (b) (4)	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:59:27

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 05:19:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:09:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:09:59
Data point term sent to Coder	System	07 Oct 2020 15:57:02
Query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 15:56:15
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 15:56:08
User entered 'GOUT bilateral feet' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 15:56:08
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:58:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:01:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:01:13
Data point term sent to Coder	System	12 Aug 2020 19:00:10

PRODUCTION RELEASE (v12.003
EAB) (1725)

562 of 2636

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
User entered 'GOUT'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2015'	Allison Crain (b) (4)	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2015'	System	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2015'	System	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 18:59:43

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
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)	12 Aug 2020 19:01:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:01:13
Data point term sent to Coder	System	12 Aug 2020 19:00:12
User entered 'BACK PAIN'	Allison Crain (b) (4)	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2005'	Allison Crain (b) (4)	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2005'	System	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2005'	System	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:00:00

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer, LLT: Thyroid cancer - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:02:10
Data point term sent to Coder	System	12 Aug 2020 19:01:12
User entered 'THYROID CANCER'	Allison Crain (b) (4)	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	12 Aug 2020 19:00:41

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:02:10
Data point term sent to Coder	System	12 Aug 2020 19:01:13
User entered 'HYPOTHYROIDISM'	Allison Crain (b) (4)	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:01:00

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:03:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:03:12
Data point term sent to Coder	System	12 Aug 2020 19:02:13
User entered 'OVERWEIGHT'	Allison Crain (b) (4)	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:01:18

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
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)	12 Aug 2020 19:03:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:03:12
Data point term sent to Coder	System	12 Aug 2020 19:02:15
User entered 'HYPERTENSION'	Allison Crain (b) (4)	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2002'	Allison Crain (b) (4)	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2002'	System	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2002'	System	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:01:33

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
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)	01 Oct 2020 08:33:04
Query 'Per DM CLR: Please note that there is no Con Brenda Anderson 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 'per patients no medication taken for this condition' (Site from DM).	(b) (4) (b) (4)	28 Sep 2020 18:23:57
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)	23 Sep 2020 11:58:34
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)	12 Aug 2020 20:54:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 20:54:22
Data point term sent to Coder	System	12 Aug 2020 20:53:26
Coding entries removed.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 20:53:08
User entered 'Atrial Fibrillation' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	12 Aug 2020 20:53:08
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:06:08

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Aug 2020 19:06:08
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	12 Aug 2020 19:05:20
User entered 'IRREGULAR HEARTBEAT'	Allison Crain (b) (4)	12 Aug 2020 19:04:24
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2010'	Allison Crain (b) (4)	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2010'	System	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2010'	System	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:04:24

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 08:33:31
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'atrial fib ' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	28 Sep 2020 18:29:35
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:01:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Pulmonary valve replacement, LLT: Pulmonary valve replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:06:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:06:08
Data point term sent to Coder	System	12 Aug 2020 19:05:20
User entered 'PULMONARY VALVE REPLACEMENT'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN Sep 2012'	Allison Crain (b) (4)	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN Sep 2012'	Allison Crain (b) (4)	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Sep 2012'	System	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2012'	System	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Sep 2012'	System	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2012'	System	12 Aug 2020 19:04:56

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Vascular disorders, HLT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Poor peripheral circulation, LLT: Poor peripheral circulation - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 12:25:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 12:25:23
Data point term sent to Coder	System	12 Aug 2020 19:06:22
User entered 'POOR CIRCULATION IN BILATERAL LEGS'	Allison Crain (b) (4)	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2000'	Allison Crain (b) (4)	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2000'	System	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2000'	System	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:05:39

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Peripheral swelling - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:14:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:14:43
Data point term sent to Coder	System	12 Aug 2020 19:07:22
User entered 'SWELLING IN BILATERAL LEGS AND FEET'	Allison Crain (b) (4)	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2000'	Allison Crain (b) (4)	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2000'	System	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2000'	System	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:06:26

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Clostridia infections, PT: Clostridium difficile infection, LLT: Clostridium difficile infection - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 04:54:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 04:54:13
Data point term sent to Coder	System	12 Aug 2020 19:07:26
User entered 'C. DIFF INFECTION'	Allison Crain (b) (4)	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2015'	Allison Crain (b) (4)	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2015'	Allison Crain (b) (4)	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2015'	System	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2015'	System	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2015'	System	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2015'	System	12 Aug 2020 19:06:54

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Psychiatric disorders, HLT: Impulse control disorders NEC, HLT: Impulse control disorders, PT: Intermittent explosive disorder, LLT: Intermittent explosive disorder - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:10:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 19:10:10
Data point term sent to Coder	System	12 Aug 2020 19:08:28
User entered 'INTERMITTENT EXPLOSIVE DISORDER'	Allison Crain (b) (4)	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2003'	Allison Crain (b) (4)	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
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	12 Aug 2020 19:08:12
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	12 Aug 2020 19:07:57
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4)	12 Aug 2020 19:08:12
User entered 'UN UNK 2003'	Allison Crain (b) (4)	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2003'	System	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2003'	System	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:08:12
User entered 'Jan 2003'	System	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 19:08:12
User entered '2003'	System	12 Aug 2020 19:07:57

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Multiple cardiac abnormalities congenital, PT: Fallot's tetralogy, LLT: Fallot's tetralogy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 11:14:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 11:14:22
Data point term sent to Coder	System	12 Aug 2020 19:21:51
User entered 'TETAROLOGY OF FALLOUT'	Allison Crain (b) (4)	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	(b) (4)	12 Aug 2020 19:22:42
User entered (b) (6) 1976' reason for change: Data Entry Error	Allison Crain (b) (4)	12 Aug 2020 19:22:42
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	12 Aug 2020 19:21:09
User entered 'UN UNK 1976'	System	12 Aug 2020 19:21:09
	Allison Crain (b) (4)	12 Aug 2020 19:21:09
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 19:22:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:22:58
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4)	12 Aug 2020 19:22:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 19:21:09
User entered empty.	System	12 Aug 2020 19:21:09
	Allison Crain (b) (4)	12 Aug 2020 19:21:09
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1978'	Allison Crain (b) (4)	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered (b) (6) 1976'	System	12 Aug 2020 19:22:42
User entered 'Jan 1976'	System	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1976'	System	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1978'	System	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1978'	System	12 Aug 2020 19:21:09

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Congenital cardiovascular anomaly therapeutic procedures, PT: Tetralogy of Fallot repair, LLT: Tetralogy of Fallot repair - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:07:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 14:07:51
Data point term sent to Coder	System	12 Aug 2020 21:00:52
User entered 'TETAROLOGY OF FALLOUT REPAIR'	Allison Crain (b) (4)	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1978'	Allison Crain (b) (4)	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1978'	Allison Crain (b) (4)	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1978'	System	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1978'	System	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1978'	System	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1978'	System	12 Aug 2020 20:59:55

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 21:10:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 21:10:12
Data point term sent to Coder	System	12 Aug 2020 21:09:19
User entered 'DEVIATED SEPTUM'	Allison Crain (b) (4)	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).	(b) (4)	12 Aug 2020 21:08:42
User entered (b) (6) 1976' reason for change: Data Entry Error	Allison Crain (b) (4)	12 Aug 2020 21:08:42
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	12 Aug 2020 21:08:27
User entered 'UN UNK 1976'	System	12 Aug 2020 21:08:27
	Allison Crain (b) (4)	12 Aug 2020 21:08:27
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered (b) (6) 1976'	System	12 Aug 2020 21:08:42
User entered 'Jan 1976'	System	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1976'	System	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 21:08:27

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Deviated septum repair - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:25:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:25:14
Data point term sent to Coder	System	12 Aug 2020 21:11:26
User entered 'SINUS SURGERY DEVIATED SEPTUM'	Allison Crain (b) (4)	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1991'	Allison Crain (b) (4)	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1991'	Allison Crain (b) (4)	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1991'	System	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1991'	System	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1991'	System	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1991'	System	12 Aug 2020 21:10:58

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Deviated septum repair - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:24:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:24:45
Data point term sent to Coder	System	12 Aug 2020 21:12:29
User entered 'SINUS SURGERY DEVIATED SEPTUM'	Allison Crain (b) (4)	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1994'	Allison Crain (b) (4)	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1994'	Allison Crain (b) (4)	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1994'	System	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1994'	System	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1994'	System	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1994'	System	12 Aug 2020 21:11:45

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Deviated septum repair - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:24:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 22:24:45
Data point term sent to Coder	System	12 Aug 2020 21:13:31
User entered 'SINUS SURGERY DEVIATED SEPTUM'	Allison Crain (b) (4)	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1995'	Allison Crain (b) (4)	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1995'	Allison Crain (b) (4)	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1995'	System	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1995'	System	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1995'	System	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1995'	System	12 Aug 2020 21:13:05

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Middle ear therapeutic procedures, PT: Tympanoplasty, LLT: Eardrum repair - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:14:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 15:14:52
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (Note: Start Date of MH #6 PERFORATED LEFT EARDRUM occurred after the date of this procedure). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 05:00:36
Data point term sent to Coder	System	07 Oct 2020 16:00:09
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (Note: Start Date of MH #6 PERFORATED LEFT EARDRUM occurred after the date of this procedure). Please verify and update as appropriate. ' answered with 'correct # 6 date' (Site from DM).	Brenda Anderson (b) (4)	07 Oct 2020 16:00:06
User entered 'PERFORATED Left EARDRUM REPAIR' reason for change: New Information	(b) (4)	07 Oct 2020 15:59:52
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (Note: Start Date of MH #6 PERFORATED LEFT EARDRUM occurred after the date of this procedure). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:01:38
Data point term sent to Coder	System	12 Aug 2020 21:15:43
User entered 'PERFORATED EARDRUM REPAIR'	Allison Crain (b) (4)	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1991'	Allison Crain (b) (4)	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 1991'	Allison Crain (b) (4)	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1991'	System	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1991'	System	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 1991'	System	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '1991'	System	12 Aug 2020 21:15:14

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 21:20:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 21:20:12
Data point term sent to Coder	System	12 Aug 2020 21:18:50
User entered 'THYROIDECTOMY'	Allison Crain (b) (4)	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	12 Aug 2020 21:18:00

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 09:05:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'oa of lower back' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 16:33:55
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:02:21
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: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:45:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:45:30
Data point term sent to Coder	System	12 Aug 2020 21:19:55
User entered 'L4-L5 DISCECTOMY'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2008'	Allison Crain (b) (4)	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2008'	Allison Crain (b) (4)	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2008'	System	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2008'	System	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2008'	System	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2008'	System	12 Aug 2020 21:19:54

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Recreational drug use - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 06:11:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 06:11:17
Data point term sent to Coder	System	12 Aug 2020 21:21:58
User entered 'FORMER RECREATIONAL DRUG USE'	Allison Crain (b) (4)	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'I'	Allison Crain (b) (4)	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2017'	Allison Crain (b) (4)	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2017'	System	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2017'	System	12 Aug 2020 21:21:23

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:29:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:29:40
Data point term sent to Coder	System	28 Sep 2020 18:28:22
User entered 'restless leg syndrome'	Brenda Anderson (b) (4)	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System (b) (4)	07 Oct 2020 16:02:35
User entered 'un UNK 2001' reason for change: New Information	Brenda Anderson (b) (4)	07 Oct 2020 16:02:35
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System (b) (4)	28 Sep 2020 18:28:03
User entered empty.	Brenda Anderson (b) (4)	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Brenda Anderson (b) (4)	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Brenda Anderson (b) (4)	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Brenda Anderson (b) (4)	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	07 Oct 2020 16:02:35
User entered empty.	System	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	07 Oct 2020 16:02:35
User entered empty.	System	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	28 Sep 2020 18:28:03

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:35:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:35:21
Data point term sent to Coder	System	07 Oct 2020 16:34:17
User entered 'osteoarthritis lower back'	Brenda Anderson (b) (4)	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'un UNK 2001'	Brenda Anderson (b) (4)	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Brenda Anderson (b) (4)	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Brenda Anderson (b) (4)	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Brenda Anderson (b) (4)	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2001'	System	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2001'	System	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered empty.	System	07 Oct 2020 16:33:21

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:23:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:23:10
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Mar 2021 18:33:19
Data point term sent to Coder	System	26 Mar 2021 17:08:26
Coding entries removed.	Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:07:54
Signature has been broken.	Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:07:54
User entered 'DEEP VEIN THROMBOSIS OF LOWER EXTREMITY' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:07:54
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:30:14
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 12:36:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 12:36:43
Data point term sent to Coder	System	16 Dec 2020 19:55:17
User entered 'HISTORY OF INTERMITTENT DEEP VEIN THROMBOSIS'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'UN UNK 2012'	Allison Crain (b) (4)	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
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	26 Mar 2021 17:07:58
Signature has been broken.	Allison Crain (b) (4)	26 Mar 2021 17:07:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Allison Crain (b) (4)	26 Mar 2021 17:07:58
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).	(b) (4) System	26 Mar 2021 17:07:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	16 Dec 2020 19:54:54
	(b) (4)	

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
Signature has been broken.	Allison Crain (b) (4)	26 Mar 2021 17:07:54
User entered 'UN UNK 2012' reason for change: Data Entry Error	Allison Crain (b) (4)	26 Mar 2021 17:07:54
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2012'	System	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2012'	System	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'Jan 2012'	System	26 Mar 2021 17:07:54
User entered empty.	System	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '2012'	System	26 Mar 2021 17:07:54
User entered empty.	System	16 Dec 2020 19:54:54

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '08:26'	Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered '12 Aug 2020 08:26'	System	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '76' in	(b) (4)	
	Allison Crain (b) (4)	12 Aug 2020 19:45:55
DataPoint set to visible.	(b) (4)	
	System	12 Aug 2020 14:36:18

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '261.2' lb	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:45:55
DataPoint set to visible.	(b) (4) System	12 Aug 2020 14:36:18

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
Amendment Manager: User entered '31.86074'	System	16 Sep 2020 23:52:59
User entered '31.9'	System	12 Aug 2020 19:45:55
DataPoint set to visible.	System	12 Aug 2020 14:36:18

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'kg/m2'	System	12 Aug 2020 19:45:55
DataPoint set to visible.	System	12 Aug 2020 14:36:18

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' and 'If Other, specify' blank. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 10:43:55
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' and 'If Other, specify' blank. Thank you.' answered with 'Updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	24 Aug 2020 17:44:28
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4) (b) (4)	24 Aug 2020 17:44:25
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' and 'If Other, specify' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 01:53:32
User entered 'Other (Other)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4)	24 Aug 2020 17:44:25
User entered missing code ND - Not Done.	Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'bpm'	System	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'breaths/min'	System	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'mmHg'	System	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User entered 'mmHg'	System	12 Aug 2020 19:45:55

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08

US3512036

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08

US3512036

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:46:05

US3512036

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 09:33:25
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 14:10:13
User entered '12 Aug 2020'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:46:05

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered (b) (6) Information Technology'	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

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 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'I'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:44:08
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 19:47:32

US3512036

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:49:04

US3512036

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	Allison Crain (b) (4)	12 Aug 2020 19:49:04

US3512036

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[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 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	12 Aug 2020 19:49:04

US3512036

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'VISIT1'	System	12 Aug 2020 19:49:04

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 13:25:02

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:47:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:47:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 13:25:02
User entered '143004' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 13:25:02

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 13:25:02

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

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 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:49:44

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

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 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	12 Aug 2020 19:49:44

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:49:44

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:49:44

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	12 Aug 2020 19:49:44

US3512036

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:39

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Complete' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:57:32
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Complete' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 16:30:04
User entered 'No (N)'	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 16:29:59
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	03 Nov 2020 13:47:07
	System	19 Sep 2020 10:18:18
	System	19 Sep 2020 06:42:00

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '08:26'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '12 Aug 2020 08:26'	System	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '99.1' F	Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '74'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'bpm'	System	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'breaths/min'	System	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '149'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 02:25:30
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Determined NCS by investigator. Subject has a history of hypertension.' (Site from System).	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:52:57
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		12 Aug 2020 19:50:52
User entered '101'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered missing code ND - Not Done.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:50:52

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	Allison Crain (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 02:26:12
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Post-dose vitals were taken 30 minutes post first IP injection per protocol.' (Site from System).	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:54:25
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 19:53:54
User entered '10:31'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '12 Aug 2020 10:31'	System	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '97.8' F	Allison Crain (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '76'	Allison Crain (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'bpm'	System	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'breaths/min'	System	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Determined NCS by investigator. Subject has a history of hypertension.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 02:25:42
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Determined NCS by investigator. Subject has a history of hypertension.' (Site from System).	Allison Crain (b) (4)	12 Aug 2020 19:55:25
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
User entered '156'	System	12 Aug 2020 19:53:54
	Allison Crain (b) (4)	12 Aug 2020 19:53:54
	(b) (4)	

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '99'	Allison Crain (b) (4)	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	12 Aug 2020 19:53:54

US3512036

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:55:32

US3512036

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:55:32

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

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 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '10:01'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '12 Aug 2020 10:01'	System	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) Taylor Johnson (b) (4)	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'ONCE'	System	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 14:36:45

US3512036

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:03

US3512036

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:03

US3512036

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '09:07'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:03

US3512036

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '12 Aug 2020 09:07'	System	12 Aug 2020 19:56:03

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:58:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12 Aug 2020'	Allison Crain (b) (4)	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '09:00'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '12 Aug 2020 09:00'	System	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered empty.	System	12 Aug 2020 19:56:19

US3512036

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:56:25

US3512036

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	12 Aug 2020 19:56:25

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:38:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aaf6da9-cd50-4c6c-8da8-6558976226c0'	System	12 Aug 2020 14:40:58
User entered 'Yes (Y)'	System	12 Aug 2020 14:40:58

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:39:05', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aaf6da9-cd50-4c6c-8da8-6558976226c0'	System	12 Aug 2020 14:40:58
User entered '97.8'	System	12 Aug 2020 14:40:58

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:39:16', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aaf6da9-cd50-4c6c-8da8-6558976226c0'	System	12 Aug 2020 14:40:58
User entered 'No (N)'	System	12 Aug 2020 14:40:58

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:39:32', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aaf6da9-cd50-4c6c-8da8-6558976226c0'	System	12 Aug 2020 14:40:58
User entered '12 Aug 2020 10:39'	System	12 Aug 2020 14:40:58

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Aug 2020 10:21'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Aug 2020 12:51'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:12', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '542712db-1786-4817-b067-91a2115dcb98'	System	13 Aug 2020 11:43:47
User entered 'Yes (Y)'	System	13 Aug 2020 11:43:47

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:18', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '542712db-1786-4817-b067-91a2115dcb98'	System	13 Aug 2020 11:43:47
User entered '98.2'	System	13 Aug 2020 11:43:47

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:22', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '542712db-1786-4817-b067-91a2115dcb98'	System	13 Aug 2020 11:43:47
User entered 'No (N)'	System	13 Aug 2020 11:43:47

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '542712db-1786-4817-b067-91a2115dcb98'	System	13 Aug 2020 11:43:47
User entered '13 Aug 2020 07:42'	System	13 Aug 2020 11:43:47

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Aug 2020 13:46'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 2'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:54', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aef903d-725c-4cf6-beed-5ad2625f6787'	System	13 Aug 2020 22:02:13
User entered 'Yes (Y)'	System	13 Aug 2020 22:02:13

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:58', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aef903d-725c-4cf6-beed-5ad2625f6787'	System	13 Aug 2020 22:02:13
User entered '98.7'	System	13 Aug 2020 22:02:13

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:02:05', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aef903d-725c-4cf6-beed-5ad2625f6787'	System	13 Aug 2020 22:02:13
User entered 'No (N)'	System	13 Aug 2020 22:02:13

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:02:09', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7aef903d-725c-4cf6-beed-5ad2625f6787'	System	13 Aug 2020 22:02:13
User entered '13 Aug 2020 18:02'	System	13 Aug 2020 22:02:13

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 3'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:46:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b6803499-5b65-4999-be07-d40deafb37d4'	System	15 Aug 2020 02:48:22
User entered 'Yes (Y)'	System	15 Aug 2020 02:48:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:46:48', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b6803499-5b65-4999-be07-d40deafb37d4' User entered '97.9'	System	15 Aug 2020 02:48:22
	System	15 Aug 2020 02:48:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:46:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b6803499-5b65-4999-be07-d40deafb37d4'	System	15 Aug 2020 02:48:22
User entered 'No (N)'	System	15 Aug 2020 02:48:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:46:56', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b6803499-5b65-4999-be07-d40deafb37d4'	System	15 Aug 2020 02:48:22
User entered '14 Aug 2020 22:46'	System	15 Aug 2020 02:48:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 4'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:02', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ea580f22-06c6-48d3-b723-418b15058fc1'	System	16 Aug 2020 00:11:22
User entered 'Yes (Y)'	System	16 Aug 2020 00:11:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ea580f22-06c6-48d3-b723-418b15058fc1'	System	16 Aug 2020 00:11:22
User entered '98.8'	System	16 Aug 2020 00:11:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:10', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ea580f22-06c6-48d3-b723-418b15058fc1'	System	16 Aug 2020 00:11:22
User entered 'No (N)'	System	16 Aug 2020 00:11:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:17', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ea580f22-06c6-48d3-b723-418b15058fc1'	System	16 Aug 2020 00:11:22
User entered '15 Aug 2020 20:11'	System	16 Aug 2020 00:11:22

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 5'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:28:51', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8b281a64-6306-4595-b29d-c4746d1e5925'	System	17 Aug 2020 01:29:10
User entered 'Yes (Y)'	System	17 Aug 2020 01:29:10

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:28:58', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8b281a64-6306-4595-b29d-c4746d1e5925'	System	17 Aug 2020 01:29:10
User entered '98.4'	System	17 Aug 2020 01:29:10

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:02', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8b281a64-6306-4595-b29d-c4746d1e5925'	System	17 Aug 2020 01:29:10
User entered 'No (N)'	System	17 Aug 2020 01:29:10

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:07', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8b281a64-6306-4595-b29d-c4746d1e5925'	System	17 Aug 2020 01:29:10
User entered '16 Aug 2020 21:29'	System	17 Aug 2020 01:29:10

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 6'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:25:56', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '03d52d27-9636-4e46-b230-b13335c3a23c'	System	18 Aug 2020 00:27:50
User entered 'Yes (Y)'	System	18 Aug 2020 00:27:50

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:16', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '03d52d27-9636-4e46-b230-b13335c3a23c'	System	18 Aug 2020 00:27:50
User entered '98.3'	System	18 Aug 2020 00:27:50

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:20', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '03d52d27-9636-4e46-b230-b13335c3a23c'	System	18 Aug 2020 00:27:50
User entered 'No (N)'	System	18 Aug 2020 00:27:50

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:24', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '03d52d27-9636-4e46-b230-b13335c3a23c'	System	18 Aug 2020 00:27:50
User entered '17 Aug 2020 20:26'	System	18 Aug 2020 00:27:50

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 7'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:01', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3f1d3bcc-dfba-4344-8f28-fa6aecd5dce1'	System	18 Aug 2020 22:56:14
User entered 'Yes (Y)'	System	18 Aug 2020 22:56:14

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:05', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3f1d3bcc-dfba-4344-8f28-fa6aecd5dce1'	System	18 Aug 2020 22:56:14
User entered '98.8'	System	18 Aug 2020 22:56:14

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:08', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3f1d3bcc-dfba-4344-8f28-fa6aecd5dce1'	System	18 Aug 2020 22:56:14
User entered 'No (N)'	System	18 Aug 2020 22:56:14

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:11', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3f1d3bcc-dfba-4344-8f28-fa6aecd5dce1'	System	18 Aug 2020 22:56:14
User entered '18 Aug 2020 18:56'	System	18 Aug 2020 22:56:14

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:41:43', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e1a89a7d-a4da-43e3-b379-90e9a4424d99'	System	12 Aug 2020 14:45:16
User entered 'None (1)'	System	12 Aug 2020 14:45:16

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:41:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e1a89a7d-a4da-43e3-b379-90e9a4424d99'	System	12 Aug 2020 14:45:16
User entered 'No (N)'	System	12 Aug 2020 14:45:16

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e1a89a7d-a4da-43e3-b379-90e9a4424d99'	System	12 Aug 2020 14:45:16
User entered 'No (N)'	System	12 Aug 2020 14:45:16

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:07', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e1a89a7d-a4da-43e3-b379-90e9a4424d99'	System	12 Aug 2020 14:45:16
User entered 'None (1)'	System	12 Aug 2020 14:45:16

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:11', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e1a89a7d-a4da-43e3-b379-90e9a4424d99'	System	12 Aug 2020 14:45:16
User entered '12 Aug 2020 10:42'	System	12 Aug 2020 14:45:16

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '12 Aug 2020 10:21'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '12 Aug 2020 12:51'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0d023a7a-f5a0-402d-b80d-a28da0959f9a'	System	13 Aug 2020 11:43:55
User entered 'None (1)'	System	13 Aug 2020 11:43:55

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:33', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0d023a7a-f5a0-402d-b80d-a28da0959f9a'	System	13 Aug 2020 11:43:55
User entered 'No (N)'	System	13 Aug 2020 11:43:55

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:39', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0d023a7a-f5a0-402d-b80d-a28da0959f9a'	System	13 Aug 2020 11:43:55
User entered 'No (N)'	System	13 Aug 2020 11:43:55

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:43', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0d023a7a-f5a0-402d-b80d-a28da0959f9a'	System	13 Aug 2020 11:43:55
User entered 'None (1)'	System	13 Aug 2020 11:43:55

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:46', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0d023a7a-f5a0-402d-b80d-a28da0959f9a'	System	13 Aug 2020 11:43:55
User entered '13 Aug 2020 07:42'	System	13 Aug 2020 11:43:55

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '12 Aug 2020 13:46'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 2'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:00:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9bc85a8-db5b-4d2a-9ec1-de089b8b5fc4'	System	13 Aug 2020 22:01:01
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 22:01:01

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:00:33', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9bc85a8-db5b-4d2a-9ec1-de089b8b5fc4'	System	13 Aug 2020 22:01:01
User entered 'No (N)'	System	13 Aug 2020 22:01:01

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:00:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9bc85a8-db5b-4d2a-9ec1-de089b8b5fc4'	System	13 Aug 2020 22:01:01
User entered 'No (N)'	System	13 Aug 2020 22:01:01

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:00:51', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9bc85a8-db5b-4d2a-9ec1-de089b8b5fc4'	System	13 Aug 2020 22:01:01
User entered 'None (1)'	System	13 Aug 2020 22:01:01

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:00:55', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9bc85a8-db5b-4d2a-9ec1-de089b8b5fc4'	System	13 Aug 2020 22:01:01
User entered '13 Aug 2020 18:00'	System	13 Aug 2020 22:01:01

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 3'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:02', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd158d1fb-f6b7-4d90-91e4-778670e8aa75'	System	15 Aug 2020 02:48:25
User entered 'None (1)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd158d1fb-f6b7-4d90-91e4-778670e8aa75'	System	15 Aug 2020 02:48:25
User entered 'No (N)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:10', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd158d1fb-f6b7-4d90-91e4-778670e8aa75'	System	15 Aug 2020 02:48:25
User entered 'No (N)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:13', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd158d1fb-f6b7-4d90-91e4-778670e8aa75'	System	15 Aug 2020 02:48:25
User entered 'None (1)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:19', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd158d1fb-f6b7-4d90-91e4-778670e8aa75'	System	15 Aug 2020 02:48:25
User entered '14 Aug 2020 22:47'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 4'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4579ac9e-d01b-40f3-b23e-c41d186fd013'	System	16 Aug 2020 00:11:39
User entered 'None (1)'	System	16 Aug 2020 00:11:39

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4579ac9e-d01b-40f3-b23e-c41d186fd013'	System	16 Aug 2020 00:11:39
User entered 'No (N)'	System	16 Aug 2020 00:11:39

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:27', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4579ac9e-d01b-40f3-b23e-c41d186fd013'	System	16 Aug 2020 00:11:39
User entered 'No (N)'	System	16 Aug 2020 00:11:39

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:29', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4579ac9e-d01b-40f3-b23e-c41d186fd013'	System	16 Aug 2020 00:11:39
User entered 'None (1)'	System	16 Aug 2020 00:11:39

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:11:33', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4579ac9e-d01b-40f3-b23e-c41d186fd013'	System	16 Aug 2020 00:11:39
User entered '15 Aug 2020 20:11'	System	16 Aug 2020 00:11:39

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 5'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:20', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fc6eca29-c357-4863-bc01-c7c5c655d212'	System	17 Aug 2020 01:29:34
User entered 'None (1)'	System	17 Aug 2020 01:29:34

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:22', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fc6eca29-c357-4863-bc01-c7c5c655d212'	System	17 Aug 2020 01:29:34
User entered 'No (N)'	System	17 Aug 2020 01:29:34

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fc6eca29-c357-4863-bc01-c7c5c655d212'	System	17 Aug 2020 01:29:34
User entered 'No (N)'	System	17 Aug 2020 01:29:34

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:27', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fc6eca29-c357-4863-bc01-c7c5c655d212'	System	17 Aug 2020 01:29:34
User entered 'None (1)'	System	17 Aug 2020 01:29:34

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fc6eca29-c357-4863-bc01-c7c5c655d212'	System	17 Aug 2020 01:29:34
User entered '16 Aug 2020 21:29'	System	17 Aug 2020 01:29:34

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 6'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:47', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bd995a0a-61f3-44bb-a551-d8079c17eb23'	System	18 Aug 2020 00:27:54
User entered 'None (1)'	System	18 Aug 2020 00:27:54

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:50', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bd995a0a-61f3-44bb-a551-d8079c17eb23'	System	18 Aug 2020 00:27:54
User entered 'No (N)'	System	18 Aug 2020 00:27:54

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:52', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bd995a0a-61f3-44bb-a551-d8079c17eb23'	System	18 Aug 2020 00:27:54
User entered 'No (N)'	System	18 Aug 2020 00:27:54

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:55', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bd995a0a-61f3-44bb-a551-d8079c17eb23'	System	18 Aug 2020 00:27:54
User entered 'None (1)'	System	18 Aug 2020 00:27:54

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:26:57', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bd995a0a-61f3-44bb-a551-d8079c17eb23'	System	18 Aug 2020 00:27:54
User entered '17 Aug 2020 20:26'	System	18 Aug 2020 00:27:54

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 7'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:15', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8ee1073d-d7f2-4524-8650-7f21d62e361b'	System	18 Aug 2020 22:56:27
User entered 'None (1)'	System	18 Aug 2020 22:56:27

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:17', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8ee1073d-d7f2-4524-8650-7f21d62e361b'	System	18 Aug 2020 22:56:27
User entered 'No (N)'	System	18 Aug 2020 22:56:27

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:20', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8ee1073d-d7f2-4524-8650-7f21d62e361b'	System	18 Aug 2020 22:56:27
User entered 'No (N)'	System	18 Aug 2020 22:56:27

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:22', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8ee1073d-d7f2-4524-8650-7f21d62e361b'	System	18 Aug 2020 22:56:27
User entered 'None (1)'	System	18 Aug 2020 22:56:27

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8ee1073d-d7f2-4524-8650-7f21d62e361b'	System	18 Aug 2020 22:56:27
User entered '18 Aug 2020 18:56'	System	18 Aug 2020 22:56:27

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:18', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered 'None (0)'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered 'None (0)'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered 'None (0)'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:31', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered 'None (0)'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered 'None (0)'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered 'None (0)'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered 'No (N)'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-12T10:42:45', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '36387593-eb43-48f4-892b-bfd5003560'	System	12 Aug 2020 14:45:27
User entered '12 Aug 2020 10:42'	System	12 Aug 2020 14:45:27

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '12 Aug 2020 10:21'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '12 Aug 2020 12:51'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered 'None (0)'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:56', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered 'None (0)'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:42:58', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered 'None (0)'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:43:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered 'None (0)'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:43:02', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered 'None (0)'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:43:05', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered 'None (0)'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:43:08', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered 'No (N)'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T07:43:10', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'c1cfc617-233d-4977-94c3-2ec6697a25d0'	System	13 Aug 2020 11:43:53
User entered '13 Aug 2020 07:43'	System	13 Aug 2020 11:43:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '12 Aug 2020 13:46'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 2'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:10', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered 'None (0)'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:29', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered 'None (0)'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:31', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered 'None (0)'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered 'None (0)'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered 'None (0)'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered 'None (0)'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:40', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered 'No (N)'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-13T18:01:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa0ec61c-a0ca-4877-a196-d8b70ce32189'	System	13 Aug 2020 22:01:47
User entered '13 Aug 2020 18:01'	System	13 Aug 2020 22:01:47

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 3'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:26', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered 'None (0)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:29', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered 'None (0)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:32', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered 'None (0)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered 'None (0)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:40', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered 'None (0)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:43', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered 'None (0)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:50', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered 'No (N)'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-14T22:47:55', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '09e3e664-22d1-4389-9e37-6f394b4f54ac'	System	15 Aug 2020 02:48:25
User entered '14 Aug 2020 22:47'	System	15 Aug 2020 02:48:25

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 4'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:27', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered 'None (0)'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:29', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered 'None (0)'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:45', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered 'None (0)'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:46', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered 'None (0)'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:48', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered 'None (0)'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:50', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered 'None (0)'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered 'No (N)'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-15T20:10:56', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9a87e59d-6ec4-49b5-b32d-78eb6720c493'	System	16 Aug 2020 00:11:00
User entered '15 Aug 2020 20:10'	System	16 Aug 2020 00:11:00

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 5'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered 'None (0)'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered 'None (0)'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered 'None (0)'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:40', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered 'None (0)'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:43', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered 'None (0)'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:45', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered 'None (0)'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:49', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered 'No (N)'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-16T21:29:52', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3fd8fe7d-f6ac-4b16-8c8a-81edf4a9a7e6'	System	17 Aug 2020 01:29:56
User entered '16 Aug 2020 21:29'	System	17 Aug 2020 01:29:56

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 6'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered 'None (0)'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:08', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered 'None (0)'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:09', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered 'None (0)'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:13', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered 'None (0)'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:14', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered 'None (0)'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:16', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered 'None (0)'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered 'No (N)'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-17T20:27:26', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ac2e3cdc-0de4-4b81-819c-dd58101aa6a9'	System	18 Aug 2020 00:27:53
User entered '17 Aug 2020 20:27'	System	18 Aug 2020 00:27:53

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 7'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:28', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered 'None (0)'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered 'None (0)'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:31', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered 'None (0)'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:33', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered 'None (0)'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered 'None (0)'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered 'None (0)'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:41', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered 'No (N)'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-08-18T18:56:44', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'b84523ce-3b9f-4968-9334-14741d5e74e3'	System	18 Aug 2020 22:56:49
User entered '18 Aug 2020 18:56'	System	18 Aug 2020 22:56:49

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 14:36:45

US3512036

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:27:28
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	19 Aug 2020 14:07:42

US3512036

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '19 Aug 2020'	(b) (4) Sheldon Warren (b) (4)	19 Aug 2020 14:07:42

US3512036

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	19 Aug 2020 14:07:42

US3512036

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Sheldon Warren (b) (4)	19 Aug 2020 14:07:42

US3512036

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	19 Aug 2020 14:07:48

US3512036

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	19 Aug 2020 14:07:48

US3512036

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Aug 2020 15:17:44

US3512036

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '26 Aug 2020'	Sheldon Warren (b) (4)	26 Aug 2020 15:17:44

US3512036

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	26 Aug 2020 15:17:44

US3512036

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Sheldon Warren (b) (4)	26 Aug 2020 15:17:44

US3512036

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	26 Aug 2020 15:17:51

US3512036

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	26 Aug 2020 15:17:51

US3512036

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:10:00

US3512036

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '3 Sep 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:10:00

US3512036

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:10:00

US3512036

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:10:00

US3512036

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	09 Sep 2020 14:10:05

US3512036

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	09 Sep 2020 14:10:05

US3512036

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:10:13

US3512036

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '9 Sep 2020'	Allison Crain (b) (4)	09 Sep 2020 14:10:13

US3512036

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[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 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	09 Sep 2020 14:10:13

US3512036

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'VISIT2'	System	09 Sep 2020 14:10:13

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '9 Sep 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '08:48'	Allison Crain (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '9 Sep 2020 08:48'	System	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '98.2' F	Allison Crain (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '77'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'bpm'	System	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '14'	Allison Crain (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'breaths/min'	System	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '136'	Allison Crain (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '77'	Allison Crain (b) (4)	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	09 Sep 2020 14:11:55

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '9 Sep 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '10:22'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '9 Sep 2020 10:22'	System	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '98.5' F	Allison Crain (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '80'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'bpm'	System	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '14'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'breaths/min'	System	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '130'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '86'	Allison Crain (b) (4)	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'mmHg'	System	09 Sep 2020 14:26:00

US3512036

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:10:18

US3512036

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	09 Sep 2020 14:10:18

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

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 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '9 Sep 2020'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '09:51'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '9 Sep 2020 09:51'	System	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4)	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'ONCE'	System	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 14:10:35

US3512036

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:11:02

US3512036

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '9 Sep 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:02

US3512036

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '09:30'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:11:02

US3512036

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '9 Sep 2020 09:30'	System	09 Sep 2020 14:11:02

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:58:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '9 Sep 2020'	Allison Crain (b) (4)	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '09:08'	Allison Crain (b) (4)	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered '9 Sep 2020 09:08'	System	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Allison Crain (b) (4) (b) (4)	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Allison Crain (b) (4)	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Allison Crain (b) (4)	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered empty.	System	09 Sep 2020 14:11:15

US3512036

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Allison Crain (b) (4)	09 Sep 2020 14:11:22

US3512036

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	09 Sep 2020 14:11:22

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:23:59', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3d04f1ad-9941-4f08-8846-f3cf99ef186d'	System	09 Sep 2020 14:24:17
User entered 'Yes (Y)'	System	09 Sep 2020 14:24:17

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:05', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3d04f1ad-9941-4f08-8846-f3cf99ef186d'	System	09 Sep 2020 14:24:17
User entered '98.5'	System	09 Sep 2020 14:24:17

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:11', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3d04f1ad-9941-4f08-8846-f3cf99ef186d'	System	09 Sep 2020 14:24:17
User entered 'No (N)'	System	09 Sep 2020 14:24:17

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:15', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '3d04f1ad-9941-4f08-8846-f3cf99ef186d'	System	09 Sep 2020 14:24:17
User entered '09 Sep 2020 10:24'	System	09 Sep 2020 14:24:17

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 10:11'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 12:41'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:14:11', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4e1c1457-5649-42f0-906a-dca37ffe54fe'	System	10 Sep 2020 00:14:34
User entered 'Yes (Y)'	System	10 Sep 2020 00:14:34

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:14:16', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4e1c1457-5649-42f0-906a-dca37ffe54fe' User entered '98.3'	System	10 Sep 2020 00:14:34
	System	10 Sep 2020 00:14:34

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:14:19', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4e1c1457-5649-42f0-906a-dca37ffe54fe'	System	10 Sep 2020 00:14:34
User entered 'Yes (Y)'	System	10 Sep 2020 00:14:34

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:14:27', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4e1c1457-5649-42f0-906a-dca37ffe54fe' User entered '0'	System	10 Sep 2020 00:14:34
	System	10 Sep 2020 00:14:34

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 10:55:33
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Brenda Anderson (b) (4)	05 Oct 2020 12:19:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:14:27', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4e1c1457-5649-42f0-906a-dca37ffe54fe'	System	10 Sep 2020 00:14:34
User entered '1'	System	10 Sep 2020 00:14:34

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:14:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4e1c1457-5649-42f0-906a-dca37ffe54fe' User entered '09 Sep 2020 20:14'	System	10 Sep 2020 00:14:34
	System	10 Sep 2020 00:14:34

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 13:36'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 2'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:01:57', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9a8a3ef-a35e-4b39-ad2e-ab2175f9c8ce'	System	11 Sep 2020 01:02:28
User entered 'Yes (Y)'	System	11 Sep 2020 01:02:28

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:01', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9a8a3ef-a35e-4b39-ad2e-ab2175f9c8ce' User entered '98.5'	System	11 Sep 2020 01:02:28
	System	11 Sep 2020 01:02:28

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9a8a3ef-a35e-4b39-ad2e-ab2175f9c8ce'	System	11 Sep 2020 01:02:28
User entered 'Yes (Y)'	System	11 Sep 2020 01:02:28

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 10:55:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:11', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9a8a3ef-a35e-4b39-ad2e-ab2175f9c8ce'	Brenda Anderson (b) (4)	05 Oct 2020 12:20:22
User entered '1'	System	11 Sep 2020 01:02:28

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:11', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9a8a3ef-a35e-4b39-ad2e-ab2175f9c8ce'	System	11 Sep 2020 01:02:28
User entered '0'	System	11 Sep 2020 01:02:28

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:15', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'e9a8a3ef-a35e-4b39-ad2e-ab2175f9c8ce'	System	11 Sep 2020 01:02:28
User entered '10 Sep 2020 21:02'	System	11 Sep 2020 01:02:28

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 3'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '39065105-cc15-4aa0-8d44-ae608ef6a17f'	System	12 Sep 2020 01:07:40
User entered 'Yes (Y)'	System	12 Sep 2020 01:07:40

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '39065105-cc15-4aa0-8d44-ae608ef6a17f' User entered '98.4'	System	12 Sep 2020 01:07:40
	System	12 Sep 2020 01:07:40

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:35', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '39065105-cc15-4aa0-8d44-ae608ef6a17f'	System	12 Sep 2020 01:07:40
User entered 'No (N)'	System	12 Sep 2020 01:07:40

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '39065105-cc15-4aa0-8d44-ae608ef6a17f'	System	12 Sep 2020 01:07:40
User entered '11 Sep 2020 21:07'	System	12 Sep 2020 01:07:40

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 4'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 5'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:01', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '521708cf-07cc-4abd-9cdd-ce253729414b'	System	13 Sep 2020 16:52:11
User entered 'Yes (Y)'	System	13 Sep 2020 16:52:11

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '521708cf-07cc-4abd-9cdd-ce253729414b' User entered '98.7'	System	13 Sep 2020 16:52:11
	System	13 Sep 2020 16:52:11

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:08', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '521708cf-07cc-4abd-9cdd-ce253729414b'	System	13 Sep 2020 16:52:11
User entered 'No (N)'	System	13 Sep 2020 16:52:11

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:10', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '521708cf-07cc-4abd-9cdd-ce253729414b'	System	13 Sep 2020 16:52:11
User entered '13 Sep 2020 12:52'	System	13 Sep 2020 16:52:11

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 6'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:33:56', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ce1f4399-c2dc-48b0-91b5-e7a3c88660bf'	System	15 Sep 2020 10:34:12
User entered 'Yes (Y)'	System	15 Sep 2020 10:34:12

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:03', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ce1f4399-c2dc-48b0-91b5-e7a3c88660bf'	System	15 Sep 2020 10:34:12
User entered '98.3'	System	15 Sep 2020 10:34:12

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:07', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ce1f4399-c2dc-48b0-91b5-e7a3c88660bf'	System	15 Sep 2020 10:34:12
User entered 'No (N)'	System	15 Sep 2020 10:34:12

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:10', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ce1f4399-c2dc-48b0-91b5-e7a3c88660bf'	System	15 Sep 2020 10:34:12
User entered '15 Sep 2020 06:34'	System	15 Sep 2020 10:34:12

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 7'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:12', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ec7aa1f9-6544-425a-8bf1-b0005352448a'	System	16 Sep 2020 02:53:30
User entered 'Yes (Y)'	System	16 Sep 2020 02:53:30

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ec7aa1f9-6544-425a-8bf1-b0005352448a'	System	16 Sep 2020 02:53:30
User entered '98.7'	System	16 Sep 2020 02:53:30

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:23', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ec7aa1f9-6544-425a-8bf1-b0005352448a'	System	16 Sep 2020 02:53:30
User entered 'No (N)'	System	16 Sep 2020 02:53:30

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:26', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'ec7aa1f9-6544-425a-8bf1-b0005352448a'	System	16 Sep 2020 02:53:30
User entered '15 Sep 2020 22:53'	System	16 Sep 2020 02:53:30

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:19', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '96589db6-8ff1-477b-bc98-9f60fc60c80f'	System	09 Sep 2020 14:24:35
User entered 'None (1)'	System	09 Sep 2020 14:24:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:22', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '96589db6-8ff1-477b-bc98-9f60fc60c80f'	System	09 Sep 2020 14:24:35
User entered 'No (N)'	System	09 Sep 2020 14:24:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:24', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '96589db6-8ff1-477b-bc98-9f60fc60c80f'	System	09 Sep 2020 14:24:35
User entered 'No (N)'	System	09 Sep 2020 14:24:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:27', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '96589db6-8ff1-477b-bc98-9f60fc60c80f'	System	09 Sep 2020 14:24:35
User entered 'None (1)'	System	09 Sep 2020 14:24:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '96589db6-8ff1-477b-bc98-9f60fc60c80f' User entered '09 Sep 2020 10:24'	System	09 Sep 2020 14:24:35
	System	09 Sep 2020 14:24:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 10:11'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 12:41'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd5408a0e-d050-42f2-8a50-8502ada82c77'	System	10 Sep 2020 00:13:49
User entered 'None (1)'	System	10 Sep 2020 00:13:49

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:29', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd5408a0e-d050-42f2-8a50-8502ada82c77'	System	10 Sep 2020 00:13:49
User entered 'No (N)'	System	10 Sep 2020 00:13:49

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd5408a0e-d050-42f2-8a50-8502ada82c77'	System	10 Sep 2020 00:13:49
User entered 'No (N)'	System	10 Sep 2020 00:13:49

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:41', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd5408a0e-d050-42f2-8a50-8502ada82c77'	System	10 Sep 2020 00:13:49
User entered 'None (1)'	System	10 Sep 2020 00:13:49

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:47', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd5408a0e-d050-42f2-8a50-8502ada82c77'	System	10 Sep 2020 00:13:49
User entered '09 Sep 2020 20:13'	System	10 Sep 2020 00:13:49

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 13:36'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 2'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:19', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd3e12dfd-9c4f-40be-a010-0ad0497ae984'	System	11 Sep 2020 01:02:43
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:02:43

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:22', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd3e12dfd-9c4f-40be-a010-0ad0497ae984'	System	11 Sep 2020 01:02:43
User entered 'No (N)'	System	11 Sep 2020 01:02:43

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:27', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd3e12dfd-9c4f-40be-a010-0ad0497ae984'	System	11 Sep 2020 01:02:43
User entered 'No (N)'	System	11 Sep 2020 01:02:43

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:32', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd3e12dfd-9c4f-40be-a010-0ad0497ae984'	System	11 Sep 2020 01:02:43
User entered 'None (1)'	System	11 Sep 2020 01:02:43

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'd3e12dfd-9c4f-40be-a010-0ad0497ae984'	System	11 Sep 2020 01:02:43
User entered '10 Sep 2020 21:02'	System	11 Sep 2020 01:02:43

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 3'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '07e5e7d8-0ffa-44df-bb3b-8cc0c9fa023c'	System	12 Sep 2020 01:07:53
User entered 'None (1)'	System	12 Sep 2020 01:07:53

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:44', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '07e5e7d8-0ffa-44df-bb3b-8cc0c9fa023c'	System	12 Sep 2020 01:07:53
User entered 'No (N)'	System	12 Sep 2020 01:07:53

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:46', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '07e5e7d8-0ffa-44df-bb3b-8cc0c9fa023c'	System	12 Sep 2020 01:07:53
User entered 'No (N)'	System	12 Sep 2020 01:07:53

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:48', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '07e5e7d8-0ffa-44df-bb3b-8cc0c9fa023c'	System	12 Sep 2020 01:07:53
User entered 'None (1)'	System	12 Sep 2020 01:07:53

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:50', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '07e5e7d8-0ffa-44df-bb3b-8cc0c9fa023c'	System	12 Sep 2020 01:07:53
User entered '11 Sep 2020 21:07'	System	12 Sep 2020 01:07:53

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 4'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 5'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:15', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '458ace97-eb4d-4891-ac25-28c1dc7a4aa5'	System	13 Sep 2020 16:52:27
User entered 'None (1)'	System	13 Sep 2020 16:52:27

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:17', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '458ace97-eb4d-4891-ac25-28c1dc7a4aa5'	System	13 Sep 2020 16:52:27
User entered 'No (N)'	System	13 Sep 2020 16:52:27

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:19', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '458ace97-eb4d-4891-ac25-28c1dc7a4aa5'	System	13 Sep 2020 16:52:27
User entered 'No (N)'	System	13 Sep 2020 16:52:27

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '458ace97-eb4d-4891-ac25-28c1dc7a4aa5'	System	13 Sep 2020 16:52:27
User entered 'None (1)'	System	13 Sep 2020 16:52:27

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:24', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '458ace97-eb4d-4891-ac25-28c1dc7a4aa5'	System	13 Sep 2020 16:52:27
User entered '13 Sep 2020 12:52'	System	13 Sep 2020 16:52:27

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 6'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:14', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9b343f4d-1e8b-4bad-99fc-576058bdebdb'	System	15 Sep 2020 10:34:25
User entered 'None (1)'	System	15 Sep 2020 10:34:25

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:17', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9b343f4d-1e8b-4bad-99fc-576058bdebdb'	System	15 Sep 2020 10:34:25
User entered 'No (N)'	System	15 Sep 2020 10:34:25

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:19', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9b343f4d-1e8b-4bad-99fc-576058bdebdb'	System	15 Sep 2020 10:34:25
User entered 'No (N)'	System	15 Sep 2020 10:34:25

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9b343f4d-1e8b-4bad-99fc-576058bdebdb'	System	15 Sep 2020 10:34:25
User entered 'None (1)'	System	15 Sep 2020 10:34:25

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:24', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9b343f4d-1e8b-4bad-99fc-576058bdebdb'	System	15 Sep 2020 10:34:25
User entered '15 Sep 2020 06:34'	System	15 Sep 2020 10:34:25

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 7'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4f36429e-3461-4b56-9e26-82339ff9f851'	System	16 Sep 2020 02:53:44
User entered 'None (1)'	System	16 Sep 2020 02:53:44

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:32', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4f36429e-3461-4b56-9e26-82339ff9f851'	System	16 Sep 2020 02:53:44
User entered 'No (N)'	System	16 Sep 2020 02:53:44

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4f36429e-3461-4b56-9e26-82339ff9f851'	System	16 Sep 2020 02:53:44
User entered 'No (N)'	System	16 Sep 2020 02:53:44

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4f36429e-3461-4b56-9e26-82339ff9f851'	System	16 Sep 2020 02:53:44
User entered 'None (1)'	System	16 Sep 2020 02:53:44

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:39', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4f36429e-3461-4b56-9e26-82339ff9f851'	System	16 Sep 2020 02:53:44
User entered '15 Sep 2020 22:53'	System	16 Sep 2020 02:53:44

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7'	System	09 Sep 2020 14:24:49
User entered 'None (0)'	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:35', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7'	System	09 Sep 2020 14:24:49
User entered 'None (0)'	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7'	System	09 Sep 2020 14:24:49
User entered 'None (0)'	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7'	System	09 Sep 2020 14:24:49
User entered 'None (0)'	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:39', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7' User entered 'None (0)'	System	09 Sep 2020 14:24:49
	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:41', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7'	System	09 Sep 2020 14:24:49
User entered 'None (0)'	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:44', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7'	System	09 Sep 2020 14:24:49
User entered 'No (N)'	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T10:24:46', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '10ec0f8d-a327-469e-b8e5-29d37bdd4bb7'	System	09 Sep 2020 14:24:49
User entered '09 Sep 2020 10:24'	System	09 Sep 2020 14:24:49

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 10:11'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 12:41'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:01', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered 'None (0)'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:04', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered 'None (0)'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered 'None (0)'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:08', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered 'None (0)'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:10', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered 'None (0)'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:13', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered 'None (0)'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:17', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered 'No (N)'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-09T20:13:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9cecf95-1eb2-486d-a262-8cb943d40b7f'	System	10 Sep 2020 00:13:22
User entered '09 Sep 2020 20:13'	System	10 Sep 2020 00:13:22

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '09 Sep 2020 13:36'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 2'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:39', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered 'None (0)'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:41', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered 'None (0)'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:43', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered 'None (0)'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:45', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered 'None (0)'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:46', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered 'None (0)'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:48', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered 'None (0)'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:51', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered 'No (N)'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-10T21:02:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '67b06c05-cad6-4b0d-bd36-235ffac9cbb4'	System	11 Sep 2020 01:02:57
User entered '10 Sep 2020 21:02'	System	11 Sep 2020 01:02:57

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 3'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:56', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered 'None (0)'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:07:58', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered 'None (0)'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:08:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered 'None (0)'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:08:02', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered 'None (0)'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:08:04', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered 'None (0)'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:08:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered 'None (0)'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:08:08', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered 'No (N)'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-11T21:08:11', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7d8325e-d339-4f84-92a7-40144a479537'	System	12 Sep 2020 01:08:13
User entered '11 Sep 2020 21:08'	System	12 Sep 2020 01:08:13

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 4'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 5'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:28', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered 'None (0)'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:30', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered 'None (0)'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:31', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered 'None (0)'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:32', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered 'None (0)'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered 'None (0)'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:35', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered 'None (0)'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:37', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered 'No (N)'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-13T12:52:40', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '2edf2a1e-5fd8-44a0-8203-c2f1c75e2710'	System	13 Sep 2020 16:52:43
User entered '13 Sep 2020 12:52'	System	13 Sep 2020 16:52:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 6'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:28', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f' User entered 'None (0)'	System	15 Sep 2020 10:34:43
	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:29', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f' User entered 'None (0)'	System	15 Sep 2020 10:34:43
	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:31', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f' User entered 'None (0)'	System	15 Sep 2020 10:34:43
	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:33', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f' User entered 'None (0)'	System	15 Sep 2020 10:34:43
	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f' User entered 'None (0)'	System	15 Sep 2020 10:34:43
	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:36', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f' User entered 'None (0)'	System	15 Sep 2020 10:34:43
	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:40', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f'	System	15 Sep 2020 10:34:43
User entered 'No (N)'	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T06:34:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '63a7dad2-bead-4d13-b614-8921bd6c213f' User entered '15 Sep 2020 06:34'	System	15 Sep 2020 10:34:43
	System	15 Sep 2020 10:34:43

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	09 Sep 2020 14:10:35
User entered 'Day 7'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered 'None (0)'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:44', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered 'None (0)'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:45', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered 'None (0)'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:47', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered 'None (0)'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:48', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered 'None (0)'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:52', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered 'None (0)'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:53:54', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered 'No (N)'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-09-15T22:54:46', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cf187d44-ee0e-4d3e-b3a9-58c3358e0266'	System	16 Sep 2020 02:54:51
User entered '15 Sep 2020 22:54'	System	16 Sep 2020 02:54:51

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 14:10:35

US3512036

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:58:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 14:10:35

US3512036

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	17 Sep 2020 17:13:32

US3512036

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '17 Sep 2020'	Sheldon Warren (b) (4)	17 Sep 2020 17:13:32

US3512036

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	17 Sep 2020 17:13:32

US3512036

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Sheldon Warren (b) (4)	17 Sep 2020 17:13:32

US3512036

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	17 Sep 2020 17:13:39

US3512036

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	17 Sep 2020 17:13:39

US3512036

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4)	
	Taylor Johnson (b) (4)	23 Sep 2020 20:53:21
	(b) (4)	

US3512036

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '23 Sep 2020'	Taylor Johnson (b) (4)	23 Sep 2020 20:53:21

US3512036

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	23 Sep 2020 20:53:21

US3512036

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Taylor Johnson (b) (4)	23 Sep 2020 20:53:21

US3512036

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	23 Sep 2020 20:53:27

US3512036

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	23 Sep 2020 20:53:27

US3512036

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	30 Sep 2020 17:16:07

US3512036

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '30 Sep 2020'	Taylor Johnson (b) (4)	30 Sep 2020 17:16:07

US3512036

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	30 Sep 2020 17:16:07

US3512036

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Taylor Johnson (b) (4)	30 Sep 2020 17:16:07

US3512036

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	30 Sep 2020 17:16:13

US3512036

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	30 Sep 2020 17:16:13

US3512036

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	07 Oct 2020 15:51:03

US3512036

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '7 Oct 2020'	Brenda Anderson (b) (4)	07 Oct 2020 15:51:03

US3512036

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[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 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	07 Oct 2020 15:51:03

US3512036

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User entered 'VISIT3'	System	07 Oct 2020 15:51:03

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '7 Oct 2020'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '08:26'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User entered '7 Oct 2020 08:26'	System	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '98.7' F	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Oral (Oral)'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '79'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User entered 'bpm'	System	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '12'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User entered 'breaths/min'	System	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '152'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User entered 'mmHg'	System	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '92'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User entered 'mmHg'	System	07 Oct 2020 15:52:15

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47

US3512036

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47

US3512036

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'No (N)'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:29

US3512036

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	Brenda Anderson (b) (4)	07 Oct 2020 15:52:29

US3512036

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:44

US3512036

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '7 Oct 2020'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:44

US3512036

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '08:36'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:44

US3512036

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:47
User entered '7 Oct 2020 08:36'	System	07 Oct 2020 15:52:44

US3512036

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	07 Oct 2020 15:52:49

US3512036

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	07 Oct 2020 15:52:49

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 64'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-14T17:43:59', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0dc2f902-00a9-46e1-a53c-38f372e4819f'	System	14 Oct 2020 21:44:13
User entered 'No (N)'	System	14 Oct 2020 21:44:13

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-14T17:44:04', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0dc2f902-00a9-46e1-a53c-38f372e4819f'	System	14 Oct 2020 21:44:13
User entered 'No (N)'	System	14 Oct 2020 21:44:13

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-14T17:44:07', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0dc2f902-00a9-46e1-a53c-38f372e4819f' User entered '14 Oct 2020 17:44:07'	System	14 Oct 2020 21:44:13
	System	14 Oct 2020 21:44:13

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 71'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-21T12:05:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '94593143-a10d-4dd7-8cbe-7978f565649b'	System	21 Oct 2020 16:05:56
User entered 'No (N)'	System	21 Oct 2020 16:05:56

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-21T12:05:50', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '94593143-a10d-4dd7-8cbe-7978f565649b'	System	21 Oct 2020 16:05:56
User entered 'No (N)'	System	21 Oct 2020 16:05:56

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-21T12:05:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '94593143-a10d-4dd7-8cbe-7978f565649b' User entered '21 Oct 2020 12:05:53'	System	21 Oct 2020 16:05:56
	System	21 Oct 2020 16:05:56

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 78'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-26T00:41:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '501f8ec7-a6fd-4776-a090-06e4a5714a57'	System	26 Oct 2020 04:41:21
User entered 'No (N)'	System	26 Oct 2020 04:41:21

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-26T00:41:15', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '501f8ec7-a6fd-4776-a090-06e4a5714a57'	System	26 Oct 2020 04:41:21
User entered 'No (N)'	System	26 Oct 2020 04:41:21

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-10-26T00:41:18', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '501f8ec7-a6fd-4776-a090-06e4a5714a57'	System	26 Oct 2020 04:41:21
User entered '26 Oct 2020 00:41:18'	System	26 Oct 2020 04:41:21

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 92'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-11-09T00:01:44', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '48c5696a-864a-4722-b637-05d0c46876e2'	System	09 Nov 2020 05:02:01
User entered 'No (N)'	System	09 Nov 2020 05:02:01

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-11-09T00:01:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '48c5696a-864a-4722-b637-05d0c46876e2'	System	09 Nov 2020 05:02:01
User entered 'No (N)'	System	09 Nov 2020 05:02:01

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-11-09T00:01:57', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '48c5696a-864a-4722-b637-05d0c46876e2'	System	09 Nov 2020 05:02:01
User entered '09 Nov 2020 00:01:57'	System	09 Nov 2020 05:02:01

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered 'Day 99'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-11-16T00:49:56', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '28a22b34-7a9f-4f1c-b370-1a91a8f88eaf'	System	16 Nov 2020 05:50:06
User entered 'No (N)'	System	16 Nov 2020 05:50:06

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-11-16T00:50:01', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '28a22b34-7a9f-4f1c-b370-1a91a8f88eaf'	System	16 Nov 2020 05:50:06
User entered 'No (N)'	System	16 Nov 2020 05:50:06

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-11-16T00:50:04', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '28a22b34-7a9f-4f1c-b370-1a91a8f88eaf'	System	16 Nov 2020 05:50:06
User entered '16 Nov 2020 00:50:04'	System	16 Nov 2020 05:50:06

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 14:36:45

US3512036

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:05
Data entry locked.	System	12 Aug 2020 14:36:45
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 14:36:45

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2020-11-23T07:16:01', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'efc3e768-fa59-4147-bcc4-46b709c1ab47'	System	23 Nov 2020 12:16:37
User entered 'No (N)'	System	23 Nov 2020 12:16:37

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2020-11-23T07:16:25', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'efc3e768-fa59-4147-bcc4-46b709c1ab47'	System	23 Nov 2020 12:16:37
User entered 'No (N)'	System	23 Nov 2020 12:16:37

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-11-23T07:16:34', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'efc3e768-fa59-4147-bcc4-46b709c1ab47'	System	23 Nov 2020 12:16:37
User entered '23 Nov 2020 07:16:34'	System	23 Nov 2020 12:16:37

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2020-12-11T01:47:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a1186b60-955e-4830-b044-d6c3e8774ab3'	System	11 Dec 2020 06:48:10
User entered 'No (N)'	System	11 Dec 2020 06:48:10

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2020-12-11T01:48:02', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a1186b60-955e-4830-b044-d6c3e8774ab3'	System	11 Dec 2020 06:48:10
User entered 'No (N)'	System	11 Dec 2020 06:48:10

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-12-11T01:48:06', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a1186b60-955e-4830-b044-d6c3e8774ab3'	System	11 Dec 2020 06:48:10
User entered '11 Dec 2020 01:48:06'	System	11 Dec 2020 06:48:10

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2020-12-19T10:25:12', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cbd53e77-63c0-4ece-9025-2e334e7baae8'	System	19 Dec 2020 15:25:24
User entered 'No (N)'	System	19 Dec 2020 15:25:24

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2020-12-19T10:25:20', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cbd53e77-63c0-4ece-9025-2e334e7baae8'	System	19 Dec 2020 15:25:24
User entered 'No (N)'	System	19 Dec 2020 15:25:24

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-12-19T10:25:23', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'cbd53e77-63c0-4ece-9025-2e334e7baae8' User entered '19 Dec 2020 10:25:23'	System	19 Dec 2020 15:25:24
	System	19 Dec 2020 15:25:24

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2020-12-25T03:55:50', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '54bc4b74-fe71-436c-ab21-7e3ccc96bc99'	System	25 Dec 2020 08:55:59
User entered 'No (N)'	System	25 Dec 2020 08:55:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2020-12-25T03:55:53', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '54bc4b74-fe71-436c-ab21-7e3ccc96bc99'	System	25 Dec 2020 08:55:59
User entered 'No (N)'	System	25 Dec 2020 08:55:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2020-12-25T03:55:55', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '54bc4b74-fe71-436c-ab21-7e3ccc96bc99'	System	25 Dec 2020 08:55:59
User entered '25 Dec 2020 03:55:55'	System	25 Dec 2020 08:55:59

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-01-01T00:02:58', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '39f101b6-41d7-411e-9e04-d81197eebaf6'	System	01 Jan 2021 05:03:09
User entered 'No (N)'	System	01 Jan 2021 05:03:09

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-01-01T00:03:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '39f101b6-41d7-411e-9e04-d81197eebaf6'	System	01 Jan 2021 05:03:09
User entered 'No (N)'	System	01 Jan 2021 05:03:09

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-01-01T00:03:02', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '39f101b6-41d7-411e-9e04-d81197eebaf6'	System	01 Jan 2021 05:03:09
User entered '01 Jan 2021 00:03:02'	System	01 Jan 2021 05:03:09

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-01-08T07:34:45', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0c63836c-91ee-49d4-a7db-47e4e8c47816'	System	08 Jan 2021 12:34:53
User entered 'No (N)'	System	08 Jan 2021 12:34:53

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-01-08T07:34:47', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0c63836c-91ee-49d4-a7db-47e4e8c47816'	System	08 Jan 2021 12:34:53
User entered 'No (N)'	System	08 Jan 2021 12:34:53

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-01-08T07:34:49', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0c63836c-91ee-49d4-a7db-47e4e8c47816'	System	08 Jan 2021 12:34:53
User entered '08 Jan 2021 07:34:49'	System	08 Jan 2021 12:34:53

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-01-15T01:30:21', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'dba65020-3e5a-4124-a153-73a7479ea690'	System	15 Jan 2021 06:30:28
User entered 'No (N)'	System	15 Jan 2021 06:30:28

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-01-15T01:30:24', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'dba65020-3e5a-4124-a153-73a7479ea690'	System	15 Jan 2021 06:30:28
User entered 'No (N)'	System	15 Jan 2021 06:30:28

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-01-15T01:30:26', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'dba65020-3e5a-4124-a153-73a7479ea690'	System	15 Jan 2021 06:30:28
User entered '15 Jan 2021 01:30:26'	System	15 Jan 2021 06:30:28

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-01-26T13:54:03', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7b7ffa6-5233-4aa9-8ec0-6d940f4650f0'	System	26 Jan 2021 19:56:29
User entered 'No (N)'	System	26 Jan 2021 19:56:29

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-01-26T13:54:05', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7b7ffa6-5233-4aa9-8ec0-6d940f4650f0'	System	26 Jan 2021 19:56:29
User entered 'No (N)'	System	26 Jan 2021 19:56:29

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-01-26T13:54:07', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'f7b7ffa6-5233-4aa9-8ec0-6d940f4650f0' User entered '26 Jan 2021 13:54:07'	System	26 Jan 2021 19:56:29
	System	26 Jan 2021 19:56:29

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-01-29T02:53:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0424eafe-1e94-49fa-b9b4-ef35e8edde70'	System	29 Jan 2021 07:53:45
User entered 'No (N)'	System	29 Jan 2021 07:53:45

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-01-29T02:53:40', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0424eafe-1e94-49fa-b9b4-ef35e8edde70'	System	29 Jan 2021 07:53:45
User entered 'No (N)'	System	29 Jan 2021 07:53:45

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-01-29T02:53:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0424eafe-1e94-49fa-b9b4-ef35e8edde70'	System	29 Jan 2021 07:53:45
User entered '29 Jan 2021 02:53:42'	System	29 Jan 2021 07:53:45

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-02-05T07:35:38', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a37c3d8c-e7d9-4b5f-8e11-ed0137a8b146'	System	05 Feb 2021 12:35:46
User entered 'No (N)'	System	05 Feb 2021 12:35:46

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-02-05T07:35:40', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a37c3d8c-e7d9-4b5f-8e11-ed0137a8b146'	System	05 Feb 2021 12:35:46
User entered 'No (N)'	System	05 Feb 2021 12:35:46

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-02-05T07:35:42', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a37c3d8c-e7d9-4b5f-8e11-ed0137a8b146'	System	05 Feb 2021 12:35:46
User entered '05 Feb 2021 07:35:42'	System	05 Feb 2021 12:35:46

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-02-12T05:43:01', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fafc35b3-762f-408a-8f62-977676426f58'	System	12 Feb 2021 10:43:10
User entered 'No (N)'	System	12 Feb 2021 10:43:10

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-02-12T05:43:03', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fafc35b3-762f-408a-8f62-977676426f58'	System	12 Feb 2021 10:43:10
User entered 'No (N)'	System	12 Feb 2021 10:43:10

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-02-12T05:43:05', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fafc35b3-762f-408a-8f62-977676426f58'	System	12 Feb 2021 10:43:10
User entered '12 Feb 2021 05:43:05'	System	12 Feb 2021 10:43:10

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-02-19T05:50:44', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '335a466a-e5c1-450b-a429-22afd4e01fe8'	System	19 Feb 2021 10:50:51
User entered 'No (N)'	System	19 Feb 2021 10:50:51

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-02-19T05:50:46', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '335a466a-e5c1-450b-a429-22afd4e01fe8'	System	19 Feb 2021 10:50:51
User entered 'No (N)'	System	19 Feb 2021 10:50:51

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-02-19T05:50:48', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '335a466a-e5c1-450b-a429-22afd4e01fe8' User entered '19 Feb 2021 05:50:48'	System	19 Feb 2021 10:50:51
	System	19 Feb 2021 10:50:51

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-02-28T12:08:50-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '49ab31ee-bb4b-40a1-86e4-27606d19fc4a' User entered 'No (N)'	System	28 Feb 2021 17:13:47
	System	28 Feb 2021 17:13:47

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-02-28T12:08:52-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '49ab31ee-bb4b-40a1-86e4-27606d19fc4a'	System	28 Feb 2021 17:13:47
User entered 'No (N)'	System	28 Feb 2021 17:13:47

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-02-28T12:08:54-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '49ab31ee-bb4b-40a1-86e4-27606d19fc4a' User entered '28 Feb 2021 12:08:54'	System	28 Feb 2021 17:13:47
	System	28 Feb 2021 17:13:47

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-03-05T07:01:08-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8d20b8e0-e29a-425a-9d4e-fd3dcf218a1e'	System	05 Mar 2021 12:01:13
User entered 'No (N)'	System	05 Mar 2021 12:01:13

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-03-05T07:01:10-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8d20b8e0-e29a-425a-9d4e-fd3dcf218a1e'	System	05 Mar 2021 12:01:13
User entered 'No (N)'	System	05 Mar 2021 12:01:13

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-03-05T07:01:14-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '8d20b8e0-e29a-425a-9d4e-fd3dcf218a1e'	System	05 Mar 2021 12:01:13
User entered '05 Mar 2021 07:01:14'	System	05 Mar 2021 12:01:13

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-03-12T04:16:39-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9ece71d5-ec2d-4ab8-984c-776a54c13b82'	System	12 Mar 2021 09:16:45
User entered 'No (N)'	System	12 Mar 2021 09:16:45

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-03-12T04:16:41-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9ece71d5-ec2d-4ab8-984c-776a54c13b82'	System	12 Mar 2021 09:16:45
User entered 'No (N)'	System	12 Mar 2021 09:16:45

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-03-12T04:16:43-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '9ece71d5-ec2d-4ab8-984c-776a54c13b82' User entered '12 Mar 2021 04:16:43'	System	12 Mar 2021 09:16:45
	System	12 Mar 2021 09:16:45

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-03-26T16:22:55-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'faefcdd6-5247-4fe4-aff6-8a51642bd255'	System	26 Mar 2021 20:23:04
User entered 'No (N)'	System	26 Mar 2021 20:23:04

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-03-26T16:22:57-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'faefcdd6-5247-4fe4-aff6-8a51642bd255'	System	26 Mar 2021 20:23:04
User entered 'No (N)'	System	26 Mar 2021 20:23:04

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-03-26T16:23:00-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'faefcdd6-5247-4fe4-aff6-8a51642bd255'	System	26 Mar 2021 20:23:04
User entered '26 Mar 2021 16:23:00'	System	26 Mar 2021 20:23:04

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-04-02T05:16:40-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a3550a1b-b9ae-4ebf-8e5f-3e5ecc1c6ad1' User entered 'No (N)'	System	02 Apr 2021 09:16:44
	System	02 Apr 2021 09:16:44

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-04-02T05:16:42-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a3550a1b-b9ae-4ebf-8e5f-3e5ecc1c6ad1' User entered 'No (N)'	System	02 Apr 2021 09:16:44
	System	02 Apr 2021 09:16:44

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-04-02T05:16:44-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'a3550a1b-b9ae-4ebf-8e5f-3e5ecc1c6ad1'	System	02 Apr 2021 09:16:44
User entered '02 Apr 2021 05:16:44'	System	02 Apr 2021 09:16:44

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-04-12T19:52:38-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0905f393-57ad-40d8-ab11-ffda27ad5144'	System	12 Apr 2021 23:52:46
User entered 'No (N)'	System	12 Apr 2021 23:52:46

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-04-12T19:52:40-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0905f393-57ad-40d8-ab11-ffda27ad5144'	System	12 Apr 2021 23:52:46
User entered 'No (N)'	System	12 Apr 2021 23:52:46

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-04-12T19:52:42-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '0905f393-57ad-40d8-ab11-ffda27ad5144'	System	12 Apr 2021 23:52:46
User entered '12 Apr 2021 19:52:42'	System	12 Apr 2021 23:52:46

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-04-16T02:07:55-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4ac8042f-ffcc-4374-bb18-42898bfc3b83'	System	16 Apr 2021 06:08:02
User entered 'No (N)'	System	16 Apr 2021 06:08:02

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-04-16T02:07:56-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4ac8042f-ffcc-4374-bb18-42898bfc3b83'	System	16 Apr 2021 06:08:02
User entered 'No (N)'	System	16 Apr 2021 06:08:02

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-04-16T02:07:58-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '4ac8042f-ffcc-4374-bb18-42898bfc3b83'	System	16 Apr 2021 06:08:02
User entered '16 Apr 2021 02:07:58'	System	16 Apr 2021 06:08:02

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-04-23T04:33:34-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bf28234e-76d7-42fc-8ea5-4491cf97c658'	System	23 Apr 2021 08:33:40
User entered 'No (N)'	System	23 Apr 2021 08:33:40

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-04-23T04:33:36-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bf28234e-76d7-42fc-8ea5-4491cf97c658'	System	23 Apr 2021 08:33:40
User entered 'No (N)'	System	23 Apr 2021 08:33:40

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-04-23T04:33:38-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'bf28234e-76d7-42fc-8ea5-4491cf97c658'	System	23 Apr 2021 08:33:40
User entered '23 Apr 2021 04:33:38'	System	23 Apr 2021 08:33:40

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[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 (9adb0173cf05ccab)', Time: '2021-05-02T17:27:22-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7e450d1a-7da6-4bf5-b8e7-e69813d67d45'	System	02 May 2021 21:27:31
User entered 'No (N)'	System	02 May 2021 21:27:31

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

Have you been exposed to someone with 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 (9adb0173cf05ccab)', Time: '2021-05-02T17:27:24-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7e450d1a-7da6-4bf5-b8e7-e69813d67d45'	System	02 May 2021 21:27:31
User entered 'No (N)'	System	02 May 2021 21:27:31

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-05-02T17:27:27-04:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: '7e450d1a-7da6-4bf5-b8e7-e69813d67d45'	System	02 May 2021 21:27:31
User entered '02 May 2021 17:27:27'	System	02 May 2021 21:27:31

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 04:35:52

US3512036

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:35:52
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 04:35:52

US3512036

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:58:39

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 19:14:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-02-28T12:09:03-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa40994f-91df-4841-85c7-86297f3873a3'	System	28 Feb 2021 17:13:51
User entered 'No (N)'	System	28 Feb 2021 17:13:51

US3512036

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:58:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:14:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9adb0173cf05ccab)', Time: '2021-02-28T12:09:06-05:00', User OID: 'PatientReportedOutcome (US3512036)', ODM File OID: 'fa40994f-91df-4841-85c7-86297f3873a3'	System	28 Feb 2021 17:13:51
User entered '28 Feb 2021 12:09:06'	System	28 Feb 2021 17:13:51

US3512036

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 17:49:56

US3512036

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '5 Nov 2020'	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 17:49:56

US3512036

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 17:49:56

US3512036

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 17:49:56

US3512036

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	05 Nov 2020 17:50:02

US3512036

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:31:28
User entered 'I'	System	05 Nov 2020 17:50:02

US3512036

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	08 Dec 2020 20:27:36

US3512036

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '8 Dec 2020'	(b) (4) Sheldon Warren (b) (4)	08 Dec 2020 20:27:36

US3512036

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	08 Dec 2020 20:27:36

US3512036

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	(b) (4) Sheldon Warren (b) (4)	08 Dec 2020 20:27:36

US3512036

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	08 Dec 2020 20:27:42

US3512036

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered 'I'	System	08 Dec 2020 20:27:42

US3512036

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:40:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 16:19:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 16:19:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 00:08:04
User entered empty; reason for change Data Entry Error	Sheldon Warren (b) (4)	05 Feb 2021 00:08:04
User entered 'Yes (Y)'	(b) (4)	
	Sheldon Warren (b) (4)	05 Feb 2021 00:06:58
	(b) (4)	

US3512036

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:40:14
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:19:45
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Feb 2021 00:08:04
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	05 Feb 2021 00:08:04
User entered empty; reason for change Data Entry Error	Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:08:04
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Feb 2021 00:06:58
User entered '4 Feb 2021'	Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:06:58

US3512036

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:40:14
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:19:45
User entered empty; reason for change Data Entry Error	Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:08:04
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	05 Feb 2021 00:06:58

US3512036

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:40:14
User entered empty.	(b) (4) Sheldon Warren (b) (4)	05 Feb 2021 00:06:58

US3512036

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	05 Feb 2021 00:08:11

US3512036

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered 'I'	System	05 Feb 2021 00:08:11

US3512036

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	05 Feb 2021 00:08:34

US3512036

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered '4 Feb 2021'	(b) (4) Sheldon Warren (b) (4)	05 Feb 2021 00:08:34

US3512036

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	05 Feb 2021 00:08:34

US3512036

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered empty.	(b) (4) Sheldon Warren (b) (4)	05 Feb 2021 00:08:34

US3512036

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:30:14
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	05 Feb 2021 00:08:41

US3512036

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered 'I'	System	05 Feb 2021 00:08:41

US3512036

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:05:57

US3512036

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 02:39:19
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Acknowledged. Subject was scheduled initially 08Mar2021, rescheduled to 16Mar2021 at 1400 but did not call or show. Left message on subject machine 16Mar2021 at 1310 and 1838. left voicemail again 26Mar2021. ' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:06
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Mar 2021 19:05:57
User entered '30 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 19:05:57

US3512036

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:05:57

US3512036

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered 'VISIT4'	System	30 Mar 2021 19:05:57

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered empty.	System	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered empty.	System	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered empty.	System	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered empty.	System	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered empty.	System	30 Mar 2021 19:14:23

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07

US3512036

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07

US3512036

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:40

US3512036

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:40

US3512036

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:05

US3512036

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:05

US3512036

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered '12:26'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:05

US3512036

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered '30 Mar 2021 12:26'	System	30 Mar 2021 19:15:05

US3512036

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:25

US3512036

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:29:07
User entered 'I'	System	30 Mar 2021 19:15:25

US3512036

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:56
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	05 Apr 2021 16:38:28

US3512036

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:56
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '5 Apr 2021'	(b) (4) Sheldon Warren (b) (4)	05 Apr 2021 16:38:28

US3512036

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:56
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	05 Apr 2021 16:38:28

US3512036

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:56
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	(b) (4) Sheldon Warren (b) (4)	05 Apr 2021 16:38:28

US3512036

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:56
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	05 Apr 2021 16:38:33

US3512036

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:28:56
User entered 'I'	System	05 Apr 2021 16:38:33

US3512036

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	Allison Crain (b) (4)	11 Feb 2021 17:21:16

US3512036

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '11 Feb 2021'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:21:16

US3512036

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[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 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Clinic (Clinic)'	(b) (4) Allison Crain (b) (4) (b) (4)	11 Feb 2021 17:21:16

US3512036

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 17:21:16

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '11 Feb 2021'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[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 21:25:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:43:40
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:18:50

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:43:40
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:18:50

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '11 Feb 2021'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'mRNA-1273 (mRNA-1273)'	Allison Crain (b) (4)	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'mRNA-1273 (mRNA-1273)'	Allison Crain (b) (4)	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'mRNA-1273 (mRNA-1273)'	Allison Crain (b) (4)	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User entered empty.	System	11 Feb 2021 17:22:30

US3512036

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User entered empty.	System	11 Feb 2021 17:22:30

US3512036

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:23:11

US3512036

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '11 Feb 2021'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:23:11

US3512036

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '11:29'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:23:11

US3512036

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User entered '11 Feb 2021 11:29'	System	11 Feb 2021 17:23:11

US3512036

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:23:25

US3512036

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '11 Feb 2021'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:23:25

US3512036

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '11:26'	(b) (4) Allison Crain (b) (4)	11 Feb 2021 17:23:25

US3512036

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:13
User entered '11 Feb 2021 11:26'	System	11 Feb 2021 17:23:25

US3512036

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:58:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:34
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:34:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:13:47
	Sheldon Warren (b) (4)	
	(b) (4)	

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:35:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Impingement syndrome shoulder - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 21:22:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 21:22:45
Data point term sent to Coder	System	17 Sep 2020 17:15:02
User entered 'Left shoulder nerve impingement'	Sheldon Warren (b) (4)	17 Sep 2020 17:14:56
	(b) (4)	

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '27 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:35:21
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:32:40
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'ongoing per source' (Site from DM).	Brenda Anderson (b) (4)	30 Nov 2020 16:02:29
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 22:32:35
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	17 Sep 2020 17:14:56
	(b) (4)	

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:22:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 13:22:08
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Sheldon Warren (b) (4) (b) (4)	18 Sep 2020 13:22:08
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:14:56
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:35:21
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 13:22:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 13:22:08
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	18 Sep 2020 13:22:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Sep 2020 17:14:56
	Sheldon Warren (b) (4)	17 Sep 2020 17:14:56
	(b) (4)	

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'None (NONE)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'I'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 17:14:56

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:35:21
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:30
User entered	System	17 Dec 2020 14:26:23
'USA-US065-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	17 Dec 2020 14:26:23

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HISTORY OF INTERMITTENT DEEP VEIN THROMBOSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:57:33
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HISTORY OF INTERMITTENT DEEP VEIN THROMBOSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'These are not intermittent and this is not a worsening. Please see updated MH log line #36.' (Site from DM).	Allison Crain (b) (4)	26 Mar 2021 17:08:38
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HISTORY OF INTERMITTENT DEEP VEIN THROMBOSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:12:19
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Venous thrombosis limb, LLT: Leg venous thrombosis - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 21:46:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 21:46:17
Data point term sent to Coder	System	12 Feb 2021 20:29:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Venous thrombosis limb, LLT: Leg venous thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 11:21:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 11:21:40
Data point term sent to Coder	System	16 Dec 2020 20:09:28
User entered 'VENOUS THROMBOSIS OF RIGHT LOWER EXTREMITY'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '2 Dec 2020'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Un-verified.	Allison Crain (b) (4)	21 Jan 2021 17:05:47
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4)	21 Jan 2021 17:05:47
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Yes (Y)'	Allison Crain (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Un-verified.	Allison Crain (b) (4)	21 Jan 2021 17:05:47
User entered '13 Dec 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	21 Jan 2021 17:05:47
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Allison Crain (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User closed 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) (4), (b) (6)	22 Jan 2021 12:50:18
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.' answered with 'UPDATED' (Site from Safety).	Allison Crain (b) (4) (b) (4)	21 Jan 2021 17:05:59
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:35:21
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)	21 Dec 2020 21:38:00
User entered empty.	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Grade 4 (Grade 4)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'I'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '11 Dec 2020'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '13 Dec 2020'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Dec 2020 21:37:35
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		22 Dec 2020 21:37:35
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	22 Dec 2020 21:37:35
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	16 Dec 2020 20:09:11
User entered 'Unknown (UNK)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'Not Applicable (NOT APPLICABLE)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered 'I'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered '0'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:50:21
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPDATED' (Site from Safety).	Allison Crain (b) (4) (b) (4)	21 Jan 2021 17:06:08
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	21 Jan 2021 17:05:47
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	21 Jan 2021 17:05:47
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:35:21
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 21:37:41
User entered 'Unknown (UNKNOWN)'	Allison Crain (b) (4) (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Un-verified.	Allison Crain (b) (4)	21 Jan 2021 17:05:47
User entered 'DEEP VEIN THROMBOSIS OF RIGHT LOWER EXTREMITY' reason for change:	Allison Crain (b) (4)	21 Jan 2021 17:05:47
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:35:21
User entered empty.	Allison Crain (b) (4)	16 Dec 2020 20:09:11
	(b) (4)	

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User closed query 'IQVIA Medical query- Please confirm if hypokalemia should be an additional SAE for this subject.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 17:47:53
Query 'IQVIA Medical query- Please confirm if hypokalemia should be an additional SAE for this subject.' answered with 'Not an SAE per sub-investigator. Will add as a separate AE' (Site from Safety).	Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:29:37
User opened query 'IQVIA Medical query- Please confirm if hypokalemia should be an additional SAE for this subject.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:37:17
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
User closed query 'PV Query: Please provide a candidate cause of hypokalemia? Is it considered to be caused by hydrochlorothiazide?' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:48:23
User entered 'SUBJECT EXPERIENCED RIGHT KNEE PAIN AND CALF SWELLING ON 02 DEC 2020. SYMPTOMS GRADUALLY BEGAN TO WORSEN AND CONTINUE UP THE INNER THIGH. SUBJECT WENT TO HIS PRIMARY CARE PHYSICIAN ON 11 DEC 2020 WHEN HE NOTICED PAIN AND SWELLING IN HIS RIGHT LOWER EXTREMITY. HIS PRIMARY CARE PHYSICIAN DIAGNOSED HIM WITH A POSSIBLE DEEP VEIN THROMBOSIS AND SENT HIM TO BAPTIST SOUTH ER. SUBJECT WAS ADMITTED ON 11 DEC 2020 AND DISCHARGED 13 DEC 2020. HE WAS STARTED ON ELIQUIS, BUT DOSAGE IS NOT KNOWN AT THIS TIME. RECORDS HAVE NOT YET BEEN RECEIVED. PAIN AND SWELLING STILL CONTINUE UPON DISCHARGE AND SUBJECT STATES HE WAS TOLD THIS WOULD TAKE MONTHS TO RESOLVE. NO COVID-TESTING DONE IN HOSPITAL PER PT.' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	11 Feb 2021 17:18:20

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide a candidate cause of hypokalemia? Is it considered to be caused by hydrochlorothiazide?' answered with 'Per sub-investigator (b) (6), a candidate cause of hypokalemia cannot be determined. Please see SAE follow up report for more info.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	11 Feb 2021 17:18:01
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 17:33:58
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No Covid-19 testing done at hospital per patient.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	19 Jan 2021 13:28:13
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	19 Jan 2021 13:27:51
User entered 'SUBJECT EXPERIENCED RIGHT KNEE PAIN AND CALF SWELLING ON 02 DEC 2020. SYMPTOMS GRADUALLY BEGAN TO WORSEN AND CONTINUE UP THE INNER THIGH. SUBJECT WENT TO HIS PRIMARY CARE PHYSICIAN ON 11 DEC 2020 WHEN HE NOTICED PAIN AND SWELLING IN HIS RIGHT LOWER EXTREMITY. HIS PRIMARY CARE PHYSICIAN DIAGNOSED HIM WITH A POSSIBLE DEEP VEIN THROMBOSIS AND SENT HIM TO BAPTIST SOUTH ER. SUBJECT WAS ADMITTED ON 11 DEC 2020 AND DISCHARGED 13 DEC 2020. HE WAS STARTED ON ELIQUIS, BUT DOSAGE IS NOT KNOWN AT THIS TIME. RECORDS HAVE NOT YET BEEN RECEIVED. PAIN AND SWELLING STILL CONTINUE UPON DISCHARGE AND SUBJECT STATES HE WAS TOLD THIS WOULD TAKE MONTHS TO RESOLVE. No Covid-testing done in hoapital per pt.' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Jan 2021 13:27:51
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:35:21

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide a candidate cause of hypokalemia? Is it considered to be caused by hydrochlorothiazide?' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:06:59
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:06:53
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)	28 Dec 2020 16:39:20
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 'data updated' (Site from Safety).	Taylor Johnson (b) (4) (b) (4)	23 Dec 2020 20:14:23
User closed query 'PV Query: Please provide results of venous doppler of lower extremity .' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:17:44
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)	23 Dec 2020 14:17:31
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:17:21
Query 'PV Query: Please provide results of venous doppler of lower extremity .' answered with 'Emailed to Safety_Moderna@iqvia.com.' (Site from Safety).	Allison Crain (b) (4) (b) (4)	22 Dec 2020 23:11:24

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Emailed to Safety_Moderna@iqvia.com.' (Site from Safety).	Allison Crain (b) (4)	22 Dec 2020 23:11:12
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Covid-19 testing not done in hospital per subject. Will review records when received to verify.' (Site from Safety).	Allison Crain (b) (4)	22 Dec 2020 17:54:39
User opened query 'PV Query: Please provide results of venous doppler of lower extremity .' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 21:38:31
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)	21 Dec 2020 21:38:22
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)	21 Dec 2020 21:38:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 21:37:18
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Dec 2020 21:41:22
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 21:41:22

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject experienced right knee pain and calf swelling on 02 DEC 2020. Symptoms gradually began to worsen and continue up the inner thigh. Subject went to his primary care physician on 11 DEC 2020 when he noticed pain and swelling in his right lower extremity. His primary care physician diagnosed him with a possible deep vein thrombosis and sent him to Baptist South ER. Subject was admitted on 11 DEC 2020 and discharged 13 DEC 2020. He was started on Eliquis, but dosage is not known at this time. Records have not yet been received. Pain and swelling still continue upon discharge and subject states he was told this would take months to resolve.' reason for change: Data Entry Error	Allison Crain (b) (4)	16 Dec 2020 21:41:22
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Dec 2020 20:09:11
User entered empty.	Allison Crain (b) (4)	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Dec 2020 20:09:11

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Sigmoid diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 21:45:53
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	12 Feb 2021 20:29:20
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Sigmoid diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 16:58:04
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	21 Jan 2021 16:57:53
User entered 'DIVERTICULOSIS OF SIGMOID COLON'	Allison Crain (b) (4)	21 Jan 2021 16:57:20
	(b) (4)	

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '13 Dec 2020'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Applicable (NOT APPLICABLE)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'I'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Allison Crain (b) (4)	21 Jan 2021 17:01:49
User entered 'Unknown (UNKNOWN)'	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 16:57:20

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:15
Data point term sent to Coder	System	12 Feb 2021 20:29:21
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:59:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 16:59:03
Data point term sent to Coder	System	21 Jan 2021 16:58:54
User entered 'CHOLELITHIASIS'	Allison Crain (b) (4) (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '13 Dec 2020'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Applicable (NOT APPLICABLE)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'I'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Allison Crain (b) (4)	21 Jan 2021 17:01:39
User entered 'Unknown (UNKNOWN)'	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 16:58:32

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HISTORY OF INTERMITTENT DEEP VEIN THROMBOSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 08:54:20
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HISTORY OF INTERMITTENT DEEP VEIN THROMBOSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'These are not intermittent and this is not a worsening. Please see updated MH log line #36.' (Site from DM).	Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:08:50
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HISTORY OF INTERMITTENT DEEP VEIN THROMBOSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:12:31
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:16
Data point term sent to Coder	System	12 Feb 2021 20:29:20
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 18:28:04

PRODUCTION RELEASE (v12.003
EAB) (1725)

2109 of 2636

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	21 Jan 2021 18:28:04 21 Jan 2021 17:01:56
User entered 'DEEP VEIN THROMBOSIS OF RIGHT LOWER EXTREMITY'	Allison Crain (b) (4) (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '13 Jan 2021'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Yes (Y)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Not Applicable (NOT APPLICABLE)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #12 and 13 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)	11 Mar 2021 07:38:29
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #12 and 13 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 started while AE was still and SAE. These medications are STILL being given at this time and the indication is this AE.' (Site from DM).	Allison Crain (b) (4) (b) (4)	04 Mar 2021 15:43:44
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #12 and 13 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 Feb 2021 23:12:39
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
User entered 'I'	Allison Crain (b) (4) (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '0'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered empty.	Allison Crain (b) (4)	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:58:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 17:01:29

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 17:34:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 17:34:27
Data point term sent to Coder	System	26 Mar 2021 17:34:09
User entered 'HYPOKALEMIA'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'No (N)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'No (N)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'No (N)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '11 Dec 2020'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	07 Apr 2021 08:44:29
' (Site from DM). Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	Brenda Anderson (b) (4) (b) (4)	05 Apr 2021 17:36:34
' answered with 'per source still ongoing' (Site from DM). User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	05 Apr 2021 09:07:52
' (Site from DM). User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Mar 2021 18:33:19
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'No (N)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'Not Related (NOT RELATED)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'Not Applicable (NOT APPLICABLE)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'I'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'Unknown (UNKNOWN)'	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	Allison Crain (b) (4)	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:58:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 17:33:19

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
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: Esophageal reflux aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 17:50:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 17:50:35
Data point term sent to Coder	System	05 Apr 2021 17:49:19
User entered 'worsening acid reflux'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '27 Jan 2021'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'No (N)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Not Applicable (NOT APPLICABLE)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'I'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered '0'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:09
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
User entered empty.	Brenda Anderson (b) (4)	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 17:49:02

US3512036

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 07:58:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 17:49:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:58:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:34
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:35:59
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:25:17

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 15:29:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 15:29:03
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	04 Mar 2021 15:28:50 04 Mar 2021 15:28:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Feb 2021 19:09:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Feb 2021 19:09:48
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	14 Feb 2021 19:08:41 14 Feb 2021 19:08:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 21:46:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 21:46:18
Data point term sent to Coder	System	12 Feb 2021 20:29:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

2213 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:28:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:28:08
Data point term sent to Coder	System	12 Aug 2020 19:27:04
User entered 'OMEPRAZOLE'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	12 Aug 2020 19:26:58
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:39:35
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)	05 Mar 2021 06:22:27
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 'Please see Med History' (Site from DM).	Allison Crain (b) (4) (b) (4)	04 Mar 2021 15:28:38
Signature has been broken.	Allison Crain (b) (4) (b) (4)	04 Mar 2021 15:28:25
User entered 'ACID REFLUX' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	04 Mar 2021 15:28:25
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)	04 Mar 2021 00:35:21
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:18:03
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	14 Feb 2021 19:08:01
Signature has been broken.	Allison Crain (b) (4) (b) (4)	14 Feb 2021 19:08:01
User entered 'HEARTBURN' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	14 Feb 2021 19:08:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'ACID REFLUX'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

PRODUCTION RELEASE (v12.003
EAB) (1725)

2216 of 2636

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '20'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4)	12 Aug 2020 19:26:58
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'once daily (QD)'	Allison Crain (b) (4)	12 Aug 2020 19:26:58
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Aug 2020 19:26:58
	Allison Crain (b) (4)	
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:50:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'This is an ongoing medication taken within 28 days prior to the first IP injection per protocol.' (Site from System).	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:27:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:26:58
User entered 'UN UNK 2011'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4)	12 Aug 2020 19:26:58
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
DataPoint Un-verified.	(b) (4) Allison Crain (b) (4)	14 Feb 2021 19:07:17
Signature has been broken.	(b) (4) Allison Crain (b) (4)	14 Feb 2021 19:07:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Allison Crain (b) (4)	14 Feb 2021 19:07:17
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
DataPoint Un-verified.	(b) (4)	
	Allison Crain (b) (4)	14 Feb 2021 19:07:17
Signature has been broken.	(b) (4)	
	Allison Crain (b) (4)	14 Feb 2021 19:07:17
User entered '26 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	14 Feb 2021 19:07:17
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.		
	Allison Crain (b) (4)	12 Aug 2020 19:26:58
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User entered '1'	System	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User entered '1'	System	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:41:23
User entered '804 (804)'	System	12 Aug 2020 19:26:58

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:16
Data point term sent to Coder	System	12 Feb 2021 20:29:20
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
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)	12 Aug 2020 19:30:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:30:06
Data point term sent to Coder	System	12 Aug 2020 19:29:07
User entered 'LEVOTHYROXINE'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'HYPOTHYROIDISM'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '137'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'ug (ug)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:51:31
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Allison Crain (b) (4)	12 Aug 2020 19:28:32
answered with 'This is an ongoing medication taken within 28 days prior to the first IP injection per protocol.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:28:25
User entered 'UN UNK 2001'	Allison Crain (b) (4)	12 Aug 2020 19:28:25
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:28:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:14
Data point term sent to Coder	System	12 Feb 2021 20:29:20
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:18:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:18:17
Data point term sent to Coder	System	12 Aug 2020 19:31:09
User entered 'ARIPIPRAZOLE'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'INTERMITTENT EXPLOSIVE DISORDER'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '10'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:52:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Allison Crain (b) (4)	12 Aug 2020 19:31:22
answered with 'This is an ongoing medication taken within 28 days prior to the first IP injection per protocol.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:30:11
User entered 'UN UNK 2017'	Allison Crain (b) (4)	12 Aug 2020 19:30:11
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:30:11

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:12
Data point term sent to Coder	System	12 Feb 2021 20:29:21
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:09:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:09:59
Data point term sent to Coder	System	07 Oct 2020 15:57:02
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 15:56:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:34:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:34:17
Data point term sent to Coder	System	12 Aug 2020 19:33:14
User entered 'ALLOPURINOL'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'GOUT bilateral feet' reason for change: New Information	Brenda Anderson (b) (4)	07 Oct 2020 15:56:33
User entered 'GOUT'	(b) (4)	
	Allison Crain (b) (4)	12 Aug 2020 19:32:27
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '100'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:52:37
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Allison Crain (b) (4)	12 Aug 2020 19:32:34
answered with 'This is an ongoing medication taken within 28 days prior to the first IP injection per protocol.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:32:27
User entered 'UN UNK 2016'	Allison Crain (b) (4)	12 Aug 2020 19:32:27
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:32:27

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:13
Data point term sent to Coder	System	12 Feb 2021 20:29:21
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:35:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:35:07
Data point term sent to Coder	System	12 Aug 2020 19:34:15
User entered 'Hydrochlorothiazide'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'HYPERTENSION'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '12.5'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 02:27:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Hydrochlorothiazide' (Site from System).	Allison Crain (b) (4)	12 Aug 2020 19:34:08
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:34:02
User entered 'UN UNK 2012'	Allison Crain (b) (4)	12 Aug 2020 19:34:02
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:34:02

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:12
Data point term sent to Coder	System	12 Feb 2021 20:29:24
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:17:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:17:46
Data point term sent to Coder	System	28 Sep 2020 18:27:19
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	28 Sep 2020 18:27:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:36:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:36:08
Data point term sent to Coder	System	12 Aug 2020 19:35:16
User entered 'GABAPENTIN'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:31:34
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'added neck and other indications' (Site from DM).	Brenda Anderson (b) (4)	28 Sep 2020 18:27:27
	(b) (4)	
User entered 'OSTEOARTHRITIS neck/back pain/restless leg syndrome' reason for change: Data Entry Error	Brenda Anderson (b) (4)	28 Sep 2020 18:27:13
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:25:48
User entered 'OSTEOARTHRITIS'	Allison Crain (b) (4)	12 Aug 2020 19:34:59
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '300'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'three times daily (TID)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:53:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'This is an ongoing medication taken within 28 days before first IP injection per protocol.' (Site from System).	Allison Crain (b) (4)	12 Aug 2020 19:35:44
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:34:59
User entered 'UN UNK 2016'	Allison Crain (b) (4)	12 Aug 2020 19:34:59
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:34:59

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
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: BENAZEPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:44:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:44:52
Data point term sent to Coder	System	12 Feb 2021 20:29:23
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
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: BENAZEPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:40:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:40:11
Data point term sent to Coder	System	12 Aug 2020 19:39:26
User entered 'BENAZEPRIL'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'HYPERTENSION'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '40'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'twice daily (BID)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:53:45
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'This is an ongoing medication taken within 28 days before first IP injection per protocol.' (Site from System).	Allison Crain (b) (4)	12 Aug 2020 19:38:58
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:38:53
User entered 'UN UNK 2012'	Allison Crain (b) (4)	12 Aug 2020 19:38:53
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:38:53

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	12 Feb 2021 20:29:23
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:41:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:41:13
Data point term sent to Coder	System	12 Aug 2020 19:40:27
User entered 'CETIRIZINE HYDROCHLORIDE'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'SEASONAL ALLERGIES'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '10'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'twice daily (BID)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:54:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'This is an ongoing medication taken within 28 days before first IP injection per protocol.' (Site from System).	Allison Crain (b) (4)	12 Aug 2020 19:39:55
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:39:50
User entered 'UN UNK 2014'	Allison Crain (b) (4)	12 Aug 2020 19:39:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:39:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:13
Data point term sent to Coder	System	12 Feb 2021 20:29:21
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:42:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 19:42:09
Data point term sent to Coder	System	12 Aug 2020 19:41:34
User entered 'IBUPROFEN'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'BACK PAIN'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '800'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'as needed (PRN)'	Allison Crain (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:55:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'This is an ongoing medication taken within 28 days before first IP injection per protocol.' (Site from System).	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:41:02
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:40:57
User entered 'UN UNK 2018'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:19:06
Signature has been broken.	(b) (4), (b) (6)	30 Mar 2021 19:19:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:19:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:27:19
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 19:19:06
Signature has been broken.	(b) (4), (b) (6)	30 Mar 2021 19:19:06
User entered '14 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Mar 2021 19:19:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User entered empty.	System	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User entered empty.	System	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:51
User entered empty.	System	12 Aug 2020 19:40:57

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 11:44:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 11:44:57
Data point term sent to Coder	System	23 Feb 2021 11:44:11
Coding entries removed.	Allison Crain (b) (4) (b) (4)	23 Feb 2021 11:44:02
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 PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:45:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:45:52
Data point term sent to Coder	System	12 Feb 2021 20:29:22
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
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 PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:59:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:59:06
Data point term sent to Coder	System	19 Aug 2020 22:58:25
Coding entries removed.	Taylor Johnson (b) (4) (b) (4)	19 Aug 2020 22:57:32

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[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 PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 17:13:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 17:13:11
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	18 Aug 2020 17:12:30 18 Aug 2020 17:12:12
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 PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:43:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 19:43:08
Data point term sent to Coder User entered 'FLUTICASONE PROPIONATE'	System Allison Crain (b) (4)	12 Aug 2020 19:42:36 12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 22:57:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 22:57:32
User entered 'seasonal allergies' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	19 Aug 2020 22:57:32
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 17:12:12
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4) (b) (4)	18 Aug 2020 17:12:12
User entered 'SEASONAL ALLERGIES'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:03:46
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'done' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 16:03:47
User entered '50' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 16:03:36
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:26:15
User entered '1'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Un-verified.	Allison Crain (b) (4)	19 Jan 2021 14:21:04
User entered 'ug (ug)' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Jan 2021 14:21:04
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	07 Oct 2020 16:03:36
User entered 'puff (PUFF)'	Allison Crain (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 03:15:24
Query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank. ' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	19 Jan 2021 14:21:12
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	19 Jan 2021 14:21:04
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Jan 2021 14:21:04
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 13:37:04
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mcg' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	07 Oct 2020 16:03:36
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'once daily (QD)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 19:56:13
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)	24 Feb 2021 04:55:49
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	23 Feb 2021 11:44:10
DataPoint Un-verified.	Allison Crain (b) (4) (b) (4)	23 Feb 2021 11:44:02
Signature has been broken.	Allison Crain (b) (4) (b) (4)	23 Feb 2021 11:44:02
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	23 Feb 2021 11:44:02
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)	22 Feb 2021 01:38:08
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:56:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'This is an ongoing medication taken within 28 days before first IP injection per protocol.' (Site from System).	Allison Crain (b) (4)	12 Aug 2020 19:42:39
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 19:42:34
User entered 'UN UNK 2010'	Allison Crain (b) (4)	12 Aug 2020 19:42:34
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:42:34

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:14
Data point term sent to Coder	System	12 Feb 2021 20:29:24
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:59:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:59:44
Data point term sent to Coder	System	17 Sep 2020 17:17:06
User entered 'ibuprofen'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Left shoulder nerve impingement'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered '400'	Sheldon Warren (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 17:16:38
	Sheldon Warren (b) (4)	
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	(b) (4)	
	Sheldon Warren (b) (4)	17 Sep 2020 17:16:38
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Sep 2020 17:16:38
	Sheldon Warren (b) (4)	
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	(b) (4)	
	Sheldon Warren (b) (4)	17 Sep 2020 17:16:38
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Sheldon Warren (b) (4)	17 Sep 2020 17:16:38
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '7 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '10 Sep 2020'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User entered '1'	System	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User entered '1'	System	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:59:35
User entered '804 (804)'	System	17 Sep 2020 17:16:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
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)	12 Feb 2021 21:46:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:13
Data point term sent to Coder	System	12 Feb 2021 20:29:24
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
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)	22 Dec 2020 22:02:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:02:32
Data point term sent to Coder	System	22 Dec 2020 22:00:40
User entered 'ELIQUIS'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'VENOUS THROMBOSIS OF RIGHT LOWER EXTREMITY'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '10'	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'twice daily (BID)'	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '14 Dec 2020'	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '20 Dec 2020'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 21:59:50
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User entered '2'	System	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User entered '1'	System	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:01:00
User entered '804 (804)'	System	22 Dec 2020 21:59:50

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
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)	12 Feb 2021 21:46:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:16
Data point term sent to Coder	System	12 Feb 2021 20:29:24
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
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)	22 Dec 2020 22:02:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:02:31
Data point term sent to Coder	System	22 Dec 2020 22:00:40
User entered 'ELIQUIS'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'VENOUS THROMBOSIS OF RIGHT LOWER EXTREMITY'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '5'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'twice daily (BID)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '21 Dec 2020'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Dec 2020 22:00:38

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:12
Data point term sent to Coder	System	12 Feb 2021 20:29:24
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:24:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:24:53
Data point term sent to Coder	System	22 Dec 2020 22:23:59
User entered 'ACETAMINOPHEN'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:23:25
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'VENOUS THROMBOSIS OF RIGHT LOWER EXTREMITY'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '650'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:23:25
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'as needed (PRN)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:23:25
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:23:25
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered '11 Dec 2020'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:23:25
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 22:48:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 22:48:23
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:48:23
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 22:23:25
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '13 Dec 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	22 Dec 2020 22:48:23
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User entered empty.	System	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User entered empty.	System	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:27:21
User entered empty.	System	22 Dec 2020 22:23:25

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:14
Data point term sent to Coder	System	12 Feb 2021 20:29:25
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:28:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:28:52
Data point term sent to Coder	System	22 Dec 2020 22:27:06
User entered 'HEPARIN'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:26:35
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'VENOUS THROMBOSIS OF RIGHT LOWER EXTREMITY'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 03:55:31
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'confirmed as is per med recs' (Site from DM).	Allison Crain (b) (4) (b) (4)	11 Feb 2021 15:51:44
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:53:43
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '6'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'mL (mL)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:26:35
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'once (ONCE)'	Allison Crain (b) (4)	22 Dec 2020 22:26:35
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered '11 Dec 2020'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:26:35
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered '0'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	(b) (4)	
	Allison Crain (b) (4)	22 Dec 2020 22:26:35
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:26:35
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '11 Dec 2020'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User entered empty.	System	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User entered empty.	System	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:40
User entered empty.	System	22 Dec 2020 22:26:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: GLUCOSE;HEPARIN SODIUM, PRODUCTSYNONYM: HEPARIN SODIUM & DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Feb 2021 21:46:15
Data point term sent to Coder	System	12 Feb 2021 20:29:25
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: GLUCOSE;HEPARIN SODIUM, PRODUCTSYNONYM: HEPARIN SODIUM & DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:30:47
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 Dec 2020 22:30:47
Data point term sent to Coder	System	22 Dec 2020 22:29:07
User entered 'HEPARIN/DEXTROSE'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'VENOUS THROMBOSIS OF RIGHT LOWER EXTREMITY'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Confirmed as is from med recs' (Site from DM).	Allison Crain (b) (4)	11 Feb 2021 15:51:32
DataPoint Un-verified.	(b) (4)	
User entered '500' reason for change: Data Entry Error	Allison Crain (b) (4)	11 Feb 2021 15:50:01
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:54:38
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '500/500'	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mL (mL)'	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered empty.	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '11 Dec 2020'	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '0'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:36:26
User entered '13 Dec 2020'	Allison Crain (b) (4) (b) (4)	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:36:26
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 16:36:26
	Allison Crain (b) (4)	22 Dec 2020 22:28:43
	(b) (4)	

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User entered empty.	System	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User entered empty.	System	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:57:45
User entered empty.	System	22 Dec 2020 22:28:43

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening ACID REFLUX during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:47:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 17:53:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 17:53:28
Data point term sent to Coder Coding entries removed.	System Brenda Anderson (b) (4)	05 Apr 2021 17:52:22 05 Apr 2021 17:51:49
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening ACID REFLUX during this timeframe; update Con Med indication or provide clarification. ' answered with 'added ae #7' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	05 Apr 2021 17:50:29
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening ACID REFLUX during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 03:21:35

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 16:02:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 16:02:08
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	04 Mar 2021 15:29:51 04 Mar 2021 15:29:02
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Feb 2021 19:10:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Feb 2021 19:10:49
Data point term sent to Coder User entered 'omeprazole'	System Allison Crain (b) (4)	14 Feb 2021 19:09:42 14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered 'No (N)'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:00:23
Signature has been broken.	Brenda Anderson (b) (4)	05 Apr 2021 17:51:49
User entered 'worsening ACID REFLUX' reason for change: Per Query Resolution	Brenda Anderson (b) (4)	05 Apr 2021 17:51:49
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:39:35
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4), (b) (6)	05 Mar 2021 06:23:01
' (Site from DM).		
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	Allison Crain (b) (4)	04 Mar 2021 15:29:19
' answered with 'Updated please see MH' (Site from DM).	(b) (4)	
Signature has been broken.	Allison Crain (b) (4)	04 Mar 2021 15:29:02
User entered 'ACID REFLUX' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Mar 2021 15:29:02
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4), (b) (6)	04 Mar 2021 00:37:07
' (Site from DM).		
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered 'heartburn'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered '20'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered 'mg (mg)'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered empty.	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered 'twice daily (BID)'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered empty.	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered '27 Jan 2021'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered '0'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered 'Yes (Y)'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered empty.	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:18:03
User entered 'No (N)'	Allison Crain (b) (4)	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Feb 2021 19:08:42

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 17:39:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:39:27
Data point term sent to Coder	System	26 Mar 2021 17:38:15
User entered 'POTASSIUM CHLORIDE'	Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'HYPOKALEMIA'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '1500'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'mg (mg)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'once (ONCE)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'Oral (ORAL)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '11 Dec 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '0'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered '11 Dec 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:38
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 18:33:19
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
User entered empty.	System	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
User entered empty.	System	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:58:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:44:25
User entered empty.	System	26 Mar 2021 17:37:18

US3512036

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:58:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'No (N)'	Allison Crain (b) (4)	11 Feb 2021 17:25:10

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered		
'USA-US065-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Michael'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Koren'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'US'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
User entered '6'	System	12 Feb 2021 15:48:52
User entered '5'	System	22 Jan 2021 12:51:30
User entered '4'	System	20 Jan 2021 17:34:26
User entered '3'	System	28 Dec 2020 16:44:47
User entered '2'	System	23 Dec 2020 14:19:59
User entered '1'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered		
'USA-US065-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Michael'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Koren'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'US'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
User entered '6'	System	12 Feb 2021 15:48:52
User entered '5'	System	22 Jan 2021 12:51:30
User entered '4'	System	20 Jan 2021 17:34:26
User entered '3'	System	28 Dec 2020 16:44:47
User entered '2'	System	23 Dec 2020 14:19:59
User entered '1'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:58:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
User entered '17/Dec/2020 08:27'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:58:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'I'	(b) (4), (b) (6)	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'USA-US065-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Michael'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Koren'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'US'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
User entered '6'	System	12 Feb 2021 15:48:52
User entered '5'	System	22 Jan 2021 12:51:30
User entered '4'	System	20 Jan 2021 17:34:26
User entered '3'	System	28 Dec 2020 16:44:47
User entered '2'	System	23 Dec 2020 14:19:59
User entered '1'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:58:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
User entered '23/Dec/2020 08:19'	System	23 Dec 2020 14:19:59

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:58:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 14:19:59

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered	System	17 Dec 2020 14:26:23
'USA-US065-2020-MRNA-1273-P301000005'		

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Michael'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Koren'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'US'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
User entered '6'	System	12 Feb 2021 15:48:52
User entered '5'	System	22 Jan 2021 12:51:30
User entered '4'	System	20 Jan 2021 17:34:26
User entered '3'	System	28 Dec 2020 16:44:47
User entered '2'	System	23 Dec 2020 14:19:59
User entered '1'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:58:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
User entered '28/Dec/2020 11:44'	System	28 Dec 2020 16:44:47

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:58:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 17:34:08
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 16:44:47

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered		
'USA-US065-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Michael'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Koren'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'US'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
User entered '6'	System	12 Feb 2021 15:48:52
User entered '5'	System	22 Jan 2021 12:51:30
User entered '4'	System	20 Jan 2021 17:34:26
User entered '3'	System	28 Dec 2020 16:44:47
User entered '2'	System	23 Dec 2020 14:19:59
User entered '1'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:58:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '20/Jan/2021 17:34'	(b) (4) System	20 Jan 2021 17:34:26

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:58:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 12:51:21
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 17:34:26

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'USA-US065-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Michael'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Koren'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'US'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
User entered '6'	System	12 Feb 2021 15:48:52
User entered '5'	System	22 Jan 2021 12:51:30
User entered '4'	System	20 Jan 2021 17:34:26
User entered '3'	System	28 Dec 2020 16:44:47
User entered '2'	System	23 Dec 2020 14:19:59
User entered '1'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:58:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '22/Jan/2021 07:51'	(b) (4) System	22 Jan 2021 12:51:30

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:58:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:48:41
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 12:51:30

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered	System	17 Dec 2020 14:26:23
'USA-US065-2020-MRNA-1273-P301000005'		

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Yes (Y)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'No (N)'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Michael'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:26:51
User entered 'Koren'	System	17 Dec 2020 14:26:23

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:34:54
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 16:44:24
User entered 'US'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
	(b) (4)	
User entered '6'	System	12 Feb 2021 15:48:52
User entered '5'	System	22 Jan 2021 12:51:30
User entered '4'	System	20 Jan 2021 17:34:26
User entered '3'	System	28 Dec 2020 16:44:47
User entered '2'	System	23 Dec 2020 14:19:59
User entered '1'	System	17 Dec 2020 14:27:03

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:58:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered '12/Feb/2021 10:48'	(b) (4) System	12 Feb 2021 15:48:52

US3512036

Folder: SAE USA-US065-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:58:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:27
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:29:18
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 15:48:52