

US3712035 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:22:58

All time stamps listed in this document are displayed in GMT

US3712035

Form: Participant Creation

Data signed: (b) (4) 04 Apr 2021 23:54:45

Generated On: 10 Jun 2021 09:22:58

Participant ID

US3712035

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

US3712035

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Date of Birth (MMM yyyy)	(b) (6) 1940
Age	80
Age Units	YEARS
Age (Derived)	80
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Date of Informed Consent (<i>dd MMM yyyy</i>)	03 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	CATARACT SURGERY
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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1945
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 1945
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1945
Start Year (derived)	1945
Stop Month and Year (derived)	JAN 1945
Stop Year (derived)	1945

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1945
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 1945
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1945
Start Year (derived)	1945
Stop Month and Year (derived)	JAN 1945
Stop Year (derived)	1945

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	KERATOSIS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	ACID RELFUX
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)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	GASTROESOPHAGEAL REFLUX DISEASE
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)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	BENIGN PROSTATIC HYPERPLASIA
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)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	VARICOCELE
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	VARICOCELE REPAIR
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	NONTRAUMATIC COMPLETE TEAR OF LEFT ROTATOR CUFF
Start date (dd MMM yyyy)	17 DEC 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)	17 DEC 2015
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2015
Start Year (derived)	2015
Stop Month and Year (derived)	DEC 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	NONTRAUMATIC COMPLETE TEAR OF LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	17 DEC 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)	17 DEC 2015
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2015
Start Year (derived)	2015
Stop Month and Year (derived)	DEC 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	NONDISPLACED FRACTURE OF LEFT ACROMION PROCESS
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

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	NONDISPLACED FRACTURE OF LEFT ACROMION PROCESS REPAIR
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

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Condition	CHARCOT JOINT OF RIGHT SHOULDER
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

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:35
Height (xxx.x)	177.0 cm
Weight (xxx.x)	76.4 kg
BMI (xxx.x)	24.38635 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:57:17

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

GROCERY STORE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:57:17

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 190389

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Height	177.0 cm
Weight	74.7 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Height	177.0 cm
Weight	74.7 kg
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)	10 SEP 2020
Time of assessment (00:00-23:59)	08:27 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:27
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Height	177.0 cm
Weight	74.7 kg
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)	10 SEP 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:19
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3712035

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 SEP 2020

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 09:44

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

US3712035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	08:47 (24 HR)
Collection date and time (derived)	10 SEP 2020 08:47

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:09:14

Generated On: 10 Jun 2021 09:22:58

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:50	10 SEP 2020 08:50
Nasopharyngeal Swab 2	No		

US3712035

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

10 SEP 2020 10:26

PC Open Date & Time

10 SEP 2020 10:04

PC Close Date & Time

10 SEP 2020 12:34

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	10 SEP 2020 20:11
PC Open Date & Time	10 SEP 2020 13:29
PC Close Date & Time	11 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 20:41

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 19:38

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

13 SEP 2020 18:23

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

14 SEP 2020 19:50

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 19:33

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **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

16 SEP 2020 20:33

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 10:27

PC Open Date & Time

10 SEP 2020 10:04

PC Close Date & Time

10 SEP 2020 12:34

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 20:15

PC Open Date & Time

10 SEP 2020 13:29

PC Close Date & Time

11 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 20:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 19:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 19:52

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 19:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 20:34

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 10:29
PC Open Date & Time	10 SEP 2020 10:04
PC Close Date & Time	10 SEP 2020 12:34

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 20:16
PC Open Date & Time	10 SEP 2020 13:29
PC Close Date & Time	11 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 20:43
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:41
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:25
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:53
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:34
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:35
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3712035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 08:51
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

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)	07 OCT 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 10:19
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3712035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 07 OCT 2020

What was the treatment time? (00:00-23:59) 09:48 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 09:48

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

US3712035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 OCT 2020
Collection time (00:00-23:59)	09:06 (24 HR)
Collection date and time (derived)	07 OCT 2020 09:06

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:09:14

Generated On: 10 Jun 2021 09:22:58

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:07	07 OCT 2020 09:07
Nasopharyngeal Swab 2	No		

US3712035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

07 OCT 2020 10:21

PC Open Date & Time

07 OCT 2020 10:08

PC Close Date & Time

07 OCT 2020 12:38

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 07 OCT 2020 19:06

PC Open Date & Time 07 OCT 2020 13:33

PC Close Date & Time 08 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.6 °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	True
PC Time Stamp	08 OCT 2020 16:41
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.7 °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

09 OCT 2020 20:46

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

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

10 OCT 2020 20:04

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 OCT 2020 19:22

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

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

99.3 °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

12 OCT 2020 21:38

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **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 OCT 2020 20:44

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

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

07 OCT 2020 10:22

PC Open Date & Time

07 OCT 2020 10:08

PC Close Date & Time

07 OCT 2020 12:38

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

250

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

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

07 OCT 2020 19:19

PC Open Date & Time

07 OCT 2020 13:33

PC Close Date & Time

08 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

650

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)**

650

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

08 OCT 2020 16:43

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

900

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)**

900

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

09 OCT 2020 20:53

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

90

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)**

80

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

10 OCT 2020 20:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

60

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)**

40

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

11 OCT 2020 19:24

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

25

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 - **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 OCT 2020 21:41

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 20:45

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 10:23
PC Open Date & Time	07 OCT 2020 10:08
PC Close Date & Time	07 OCT 2020 12:38

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 19:20
PC Open Date & Time	07 OCT 2020 13:33
PC Close Date & Time	08 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 16:46
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 20:56
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 20:08
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 19:25
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 21:41
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 20:46
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3712035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:17

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3712035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3712035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 NOV 2020
Collection time (00:00-23:59)	09:05 (24 HR)
Collection date and time (derived)	04 NOV 2020 09:05

US3712035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:57:18

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 13:27:01

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 12:01:18

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 07:50:32
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 10:19:18
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 10:50:12

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 12:02:39
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 09:04:58

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 00:27:36

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 00:39:46

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 00:13:48
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 09:15:16

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 00:05:20

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

30 JAN 2021 14:53:34

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 08:17:30

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 12:56:32

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 00:01:42

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 05:04:02

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 09:42:01

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 00:03:03

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

20 MAR 2021 00:29:10

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 00:07:05

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 10:06:07

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 00:05:55

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 APR 2021 00:04:38
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 07:41:39

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 00:03:02
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 271

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 390

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

Patient Cloud Open Date & Time	22 OCT 2022 00:01
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Patient Cloud Close Date & Time	26 OCT 2022 23:59
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US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3712035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:22:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 15:26:57

US3712035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 02:28:21

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:28:21

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712035

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3712035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3712035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3712035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Was the sample collected? Yes ☐
No ☐

Collection date (*dd MMM yyyy*) _____
Collection time (*00:00-23:59*) _____
Collection date and time (derived) _____

US3712035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712035

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:58

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"/>

US3712035

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:22:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Date of updated informed consent (dd MMM yyyy) 22 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) 22 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 _____

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00-23:59)

09:46 (24 HR)

Collection date and time (derived)

22 FEB 2021 09:46

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00 - 23:59)	09:47
Collection Date and Time (derived)	22 FEB 2021 09:47

US3712035

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:18:38

Generated On: 10 Jun 2021 09:22:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3712035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

AEID USA-US068-2020-MRNA-1273-P30
1000005

Adverse event WORSENING OF LEFT
SHOULDER ACROMIAL
FRACTURE

Was this a medically-attended AE? Yes ☒
No ☐

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 22 OCT 2020

Hospital Discharge Date (dd MMM yyyy) 23 OCT 2020

Admitted to ICU? Yes ☐
No ☒

PRODUCTION RELEASE (v12.003 345 of 2709
EAB) (1725)

US3712035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
<hr/>		
Persistent or significant disability or incapacity		False
<hr/>		
Congenital anomaly or birth defect		False
<hr/>		
Other medically important event		False
<hr/>		
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
<hr/>		
None		False
<hr/>		
Concomitant Medication		True
<hr/>		
Concomitant Procedure		True
<hr/>		
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		

US3712035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SUBJECT PRESENTED AT
PHYSICIAN'S OFFICE WITH
LEFT SHOULDER PAIN. X-RAYS
TAKEN OF SHOULDER
REVEALED A CHRONIC
ACROMIAL FRACTURE. MRI OF
ROTATOR CUFF WAS DONE
SHOWING MARKED
INFLAMMATORY CHANGE
WITH THE JOINT. CT SCAN OF
THE LEFT SHOULDER SHOWED
SEVERE GLENOHUMERAL
JOINT ARTHRITIS WITH THE
UNUNITED ACROMIAL
FRACTURE. SUBJECT HAS
HISTORY WITH
OSTEOARTHRITIS ON
SHOULDERS STARTING IN 2013.
SUBJECT WAS CONSULTED
WITH RESULTS. SUBJECT WAS
IN AGREEMENT TO PROCEED
WITH REVERSE
ARTHROPLASTY. SUBJECT
WAS ADMITTED TO PARKWEST
MEDICAL CENTER ON
22OCT2020 FOR PROCEDURE OF
REVERSE ARTHROPLASTY.
SUBJECT WAS DISCHARGED TO
HOME ON 23OCT2020.
SARS-COV-2 TESTING
(APTIMA®
SARS-COV-2 ASSAY) WAS
COMPLETED AT PARKWEST
MEDICAL CENTER ON
19OCT2020, RESULT WAS
NEGATIVE.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

AEID	
Adverse event	MILD ANEMIA
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)	28 SEP 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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:38:37

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with 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)	

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 04 Apr 2021 23:54:46

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
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"/>

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 145

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication PROSCAR

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication ESCITALOPRÁM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 20

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication VITAMIN B COMPLEX

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC RHINITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication UBIQUINOL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication IRON VITRON C

Prophylaxis Yes ☐
No ☒

Indication MILD ANEMIA

Dose per administration 125

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PRE AND POST OP BLOOD CLOT
PROPHYLAXIS

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication VITRON-C PLUS IRON

Prophylaxis Yes ☒
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 125/65

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication RANITIDINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
GASTROESOPHAGEAL REFLUX
DISEASE DURING
HOSPITALIZATION

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 12 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication ASCORBIC ACID CARBONYL
IRON

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 125-65

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
HYPERLIPIDEMIA DURING
HOSPITALIZATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication DULCOLAX

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION DUE TO PAIN
MEDICATION DURING
HOSPITALIZATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF INFECTION
DUE TO SURGICAL
INTERVENTION DURING
HOSPITALIZATION

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

EVERY 8 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication LACTATED RINGERS

Prophylaxis Yes ☒
No ☐

Indication ELECTROLYTE AND FLUID
REPLACEMENT DUE TO
SURGERY DURING
HOSPITALIZATION

Dose per administration 1000

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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Name of Medication LORATADINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF SEASONAL
ALLERGIES DURING
HOSPITALIZATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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Name of Medication MORPHINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN DUE TO
SURGERY DURING
HOSPITALIZATION

Dose per administration 1

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 2 HOURS AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication OXYCODONE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN DUE TO
SURGERY DURING
HOSPITALIZATION

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

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication OXYCODONE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN DUE TO
SURGERY DURING
HOSPITALIZATION

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

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication VANCOMYCIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF INFECTION
DUE TO SURGERY DURING
HOSPITALIZATION

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

Name of Medication NAPROXEN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN DUE TO
SURGERY DURING
HOSPITALIZATION

Dose per administration 220

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 12 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 18 Apr 2021 23:27:46

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

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Data signed: (b) (4) 18 Apr 2021 23:27:46

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Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 18 Apr 2021 23:27:46

Generated On: 10 Jun 2021 09:22:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 04 Apr 2021 23:54:46

Generated On: 10 Jun 2021 09:22:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 OCT 2020	LEFT SHOULDER, REVERSE ARTHROPLASTY	Adverse Event	
22 OCT 2020	X-RAY OF LEFT SHOULDER	Adverse Event	
22 OCT 2020	MRI OF LEFT ROTATORS CUFF	Adverse Event	
22 OCT 2020	CT SCAN	Adverse Event	

US3712035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:58

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

US3712035

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:22:58

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	17/DEC/2020 09:17
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	06/JAN/2021 13:02
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/FEB/2021 14:12
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/FEB/2021 09:55
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/FEB/2021 08:50
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/MAR/2021 10:01
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	05/MAR/2021 08:36
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/APR/2021 15:04
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

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Data signed: (b) (4) 23 Apr 2021 21:38:37

Generated On: 10 Jun 2021 09:22:58

SAEID	USA-US068-2020-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	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	19/APR/2021 11:07
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

US3712035 (Prod: Alliance for Multispecialty Research, LLC)

US3712035

Form: Participant Creation

Generated On: 10 Jun 2021 09:22:58

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'US3712035'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:39:51

US3712035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:12:58

US3712035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:39:52

US3712035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:12:58

US3712035

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'SCRN'	System	03 Sep 2020 20:12:58

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered (b) (6) 1940'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:39:53

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '80'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'YEARS'	System	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '80'	System	03 Sep 2020 20:14:01

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:13:47

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:14:01

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Sep 2020'	System	03 Sep 2020 20:14:01

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2020'	System	03 Sep 2020 20:14:01

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:14:01

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:50:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 09:55:49
Query 'Data is required. Please complete.' answered with 'pending randomization' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 20:14:03
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:14:01
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:14:01

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:14:01

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:14:01

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:14:01

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:39:52

US3712035

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'I'	System	10 Sep 2020 13:51:03

US3712035

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:22:58

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:51:03

US3712035

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:22:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:10:45

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:12:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:12:54
Data point term sent to Coder	System	10 Sep 2020 16:11:53
User entered 'seasonal allergic rhinitis'	(b) (4), (b) (6)	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un Feb 2019'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Feb 2019'	System	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2019'	System	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:11:14

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	(b) (4)	10 Sep 2020 16:12:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:12:55
Data point term sent to Coder	(b) (4)	10 Sep 2020 16:11:53
User entered 'presbyopia'	System	10 Sep 2020 16:11:27
	(b) (4), (b) (6)	

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 1950'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1950'	System	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1950'	System	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:11:27

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 16:13:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:13:42
Data point term sent to Coder	System	10 Sep 2020 16:12:54
User entered 'cataract surgery'	(b) (4), (b) (6)	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	10 Sep 2020 16:11:54

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:13:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:13:42
Data point term sent to Coder	System	10 Sep 2020 16:12:54
User entered 'tonsillitis'	(b) (4), (b) (6)	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 1945'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 1945'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1945'	System	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1945'	System	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1945'	System	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1945'	System	10 Sep 2020 16:12:13

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:13:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:13:42
Data point term sent to Coder	System	10 Sep 2020 16:12:54
User entered 'tonsillectomy'	(b) (4), (b) (6)	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 1945'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 1945'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1945'	System	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1945'	System	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1945'	System	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1945'	System	10 Sep 2020 16:12:27

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth impacted, LLT: Impacted wisdom tooth - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:13:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:13:42
Data point term sent to Coder	System	10 Sep 2020 16:12:54
User entered 'wisdom teeth impaction'	(b) (4), (b) (6)	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jul 2020'	System	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2020'	System	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jul 2020'	System	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2020'	System	10 Sep 2020 16:12:53

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:14:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:14:47
Data point term sent to Coder	System	10 Sep 2020 16:13:56
User entered 'wisdom teeth extraction'	(b) (4), (b) (6)	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jul 2020'	System	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2020'	System	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jul 2020'	System	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2020'	System	10 Sep 2020 16:13:16

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Hyperkeratoses, PT: Hyperkeratosis, LLT: Keratosis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:14:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:14:49
Data point term sent to Coder	System	10 Sep 2020 16:13:57
User entered 'keratosis'	(b) (4), (b) (6)	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1995'	System	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1995'	System	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:13:49

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:15:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:15:44
Data point term sent to Coder	System	10 Sep 2020 16:15:00
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un Aug 2019'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Aug 2019'	System	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2019'	System	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:14:15

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
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)	10 Sep 2020 16:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:15:43
Data point term sent to Coder	System	10 Sep 2020 16:15:03
User entered 'acid relflux'	(b) (4), (b) (6)	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2000'	System	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2000'	System	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:14:30

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:15:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:15:44
Data point term sent to Coder	System	10 Sep 2020 16:15:03
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2000'	System	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2000'	System	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:14:50

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:16:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:16:41
Data point term sent to Coder	System	10 Sep 2020 16:16:04
User entered 'inguinal hernia'	(b) (4), (b) (6)	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:15:19

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:17:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:17:45
Data point term sent to Coder	System	10 Sep 2020 16:17:05
User entered 'inguinal hernia repair'	(b) (4), (b) (6)	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:16:13

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:17:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:17:44
Data point term sent to Coder	System	10 Sep 2020 16:17:05
User entered 'umbilical hernia'	(b) (4), (b) (6)	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:16:38

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:19:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:19:49
Data point term sent to Coder	System	10 Sep 2020 16:18:09
User entered 'umbilical hernia repair'	(b) (4), (b) (6)	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	10 Sep 2020 16:17:22

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:19:48
Data point term sent to Coder	System	10 Sep 2020 16:18:10
User entered 'Benign prostatic hyperplasia'	(b) (4), (b) (6)	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2000'	System	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2000'	System	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:17:39

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 22:25:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 22:25:40
Data point term sent to Coder	System	01 Mar 2021 13:41:07
Coding entries removed.	(b) (4), (b) (6)	01 Mar 2021 13:40:48
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 13:40:48
User entered 'OSTEOARTHRITIS (hands, shoulder, right knee)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 13:40:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:19:48
Data point term sent to Coder	System	10 Sep 2020 16:18:10
User entered 'osteoarthritis'	(b) (4), (b) (6)	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2013'	System	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2013'	System	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:18:04

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:20:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:20:42
Data point term sent to Coder	System	10 Sep 2020 16:19:11
User entered 'Insomnia'	(b) (4), (b) (6)	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2012'	System	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2012'	System	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:18:16

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:20:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:20:42
Data point term sent to Coder	System	10 Sep 2020 16:19:11
User entered 'anxiety'	(b) (4), (b) (6)	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2018'	System	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2018'	System	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	10 Sep 2020 16:18:37

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	01 Apr 2021 14:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Apr 2021 14:26:28
Data point term sent to Coder	System	01 Apr 2021 14:25:45
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	01 Apr 2021 14:25:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Apr 2021 14:25:45
User closed query 'CDM-Coding: The verbatim LEFT ANTERIOR DESCENDING ARTERY cannot be referenced as reported and appears to be incomplete. Please complete the condition/event being reported, or otherwise clarify. Please make your changes to the reported term. Thank you. ' (Site from System).	System	01 Apr 2021 14:24:56
Query 'CDM-Coding: The verbatim LEFT ANTERIOR DESCENDING ARTERY cannot be referenced as reported and appears to be incomplete. Please complete the condition/event being reported, or otherwise clarify. Please make your changes to the reported term. Thank you. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 14:24:56
Data point term sent to Coder	System	01 Apr 2021 14:24:44
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 14:24:42
User entered 'Coronary Artery Disease' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 14:24:42

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: The verbatim LEFT ANTERIOR DESCENDING ARTERY cannot be referenced as reported and appears to be incomplete. Please complete the condition/event being reported, or otherwise clarify. Please make your changes to the reported term. Thank you. (Site from System).	Coder Import (b) (4)	30 Mar 2021 10:32:55
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
Data point term sent to Coder	(b) (4)	
User entered 'left anterior descending artery'	System	01 Mar 2021 13:39:05
	(b) (4), (b) (6)	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un Jun 2018'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jun 2018'	System	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2018'	System	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	01 Mar 2021 13:38:55

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User coded data point as SOC: Reproductive system and breast disorders, HLG: Penile and scrotal disorders (excl infections and inflammations), HLT: Scrotal disorders NEC, PT: Varicocele, LLT: Varicocele - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 13:40:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 13:40:49
Data point term sent to Coder	System	01 Mar 2021 13:40:05
User entered 'varicocele'	(b) (4), (b) (6)	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1972'	System	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1972'	System	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1972'	System	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1972'	System	01 Mar 2021 13:40:05

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Testicular and scrotal therapeutic procedures, PT: Varicocele repair, LLT: Varicocele repair - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 13:41:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 13:41:49
Data point term sent to Coder	System	01 Mar 2021 13:41:06
User entered 'varicocele repair'	(b) (4), (b) (6)	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1972'	System	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1972'	System	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 1972'	System	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '1972'	System	01 Mar 2021 13:40:19

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Complete rupture of rotator cuff - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:51:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:51:54
User signature succeeded.	William Smith (b) (4) (b) (4)	10 Mar 2021 02:28:21
Data point term sent to Coder	System	01 Mar 2021 13:53:16
User entered 'nontraumatic complete tear of left rotator cuff'	(b) (4), (b) (6)	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '17 Dec 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '17 Dec 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Dec 2015'	System	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Dec 2015'	System	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:52:28

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:51:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:51:55
User signature succeeded.	William Smith (b) (4) (b) (4)	10 Mar 2021 02:28:21
Data point term sent to Coder	System	01 Mar 2021 13:53:16
User entered 'nontraumatic complete tear of left rotator cuff repair'	(b) (4), (b) (6)	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '17 Dec 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '17 Dec 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Dec 2015'	System	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Dec 2015'	System	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:52:44

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Scapula fracture, LLT: Scapula fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:53:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:53:53
User signature succeeded.	William Smith (b) (4) (b) (4)	10 Mar 2021 02:28:21
Data point term sent to Coder	System	01 Mar 2021 13:57:19
User entered 'nondisplaced fracture of left acromion process'	(b) (4), (b) (6)	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:56:46

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:53:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:53:10
User signature succeeded.	William Smith (b) (4) (b) (4)	10 Mar 2021 02:28:21
Data point term sent to Coder	System	01 Mar 2021 13:57:19
User entered 'nondisplaced fracture of left acromion process repair'	(b) (4), (b) (6)	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:57:02

US3712035

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:22:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Neuropathic arthropathy, LLT: Charcot's joint - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:51:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:51:37
User signature succeeded.	William Smith (b) (4) (b) (4)	10 Mar 2021 02:28:21
Data point term sent to Coder	System	01 Mar 2021 13:59:20
User entered 'charcot joint of right shoulder'	(b) (4), (b) (6)	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'Un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:22:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (27)

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[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:00

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Folder: Screening

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Generated On: 10 Jun 2021 09:22:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (27)

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[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2015'	System	01 Mar 2021 13:59:00

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Form: Medical History (27)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2015'	System	01 Mar 2021 13:59:00

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Spinal osteoarthritis, LLT: Cervical spondylosis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:00:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:00:50
Data point term sent to Coder	System	01 Mar 2021 14:00:21
User entered 'cervical spondylosis'	(b) (4), (b) (6)	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'Jan 2010'	System	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '2010'	System	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:22:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	01 Mar 2021 13:59:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	10 Sep 2020 16:08:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Sep 2020 16:08:41
User entered '14:35' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:08:41
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 16:08:32
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '03 Sep 2020 14:35'	System	10 Sep 2020 16:08:41
User entered empty.	System	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '177.0' cm	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32
DataPoint set to visible.	System	10 Sep 2020 13:51:03

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '76.4' kg	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32
DataPoint set to visible.	System	10 Sep 2020 13:51:03

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '24.38635'	System	10 Sep 2020 16:08:32
DataPoint set to visible.	System	10 Sep 2020 13:51:03

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'kg/m2'	System	10 Sep 2020 16:08:32
DataPoint set to visible.	System	10 Sep 2020 13:51:03

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '62'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'bpm'	System	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '18'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'breaths/min'	System	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '134'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'mmHg'	System	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '76'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'mmHg'	System	10 Sep 2020 16:08:32

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48

US3712035

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48

US3712035

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:08:48

US3712035

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
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 14:49:53
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 16:31:36
User entered '03 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 16:08:48

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

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 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

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 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Grocery store'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:39

US3712035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:31:36

US3712035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:31:36

US3712035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:31:36

US3712035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'VISIT1'	System	10 Sep 2020 16:31:36

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:04:54

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '190389'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:04:54

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:04:54

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:51:56

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:51:56

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:51:56

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:51:56

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:51:56

US3712035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:58

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:53:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:14:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:14:40

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '177.0' cm	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '74.7' kg	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '177.0' cm	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '74.7' kg	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '08:27'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '10 Sep 2020 08:27'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '66'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'bpm'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '12'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'breaths/min'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '117'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '76'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '177.0' cm	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '74.7' kg	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10:19'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '10 Sep 2020 10:19'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '65'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'bpm'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'breaths/min'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '118'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '75'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	10 Sep 2020 16:32:59

US3712035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:39:56

US3712035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:39:56

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '09:44'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '10 Sep 2020 09:44'	System	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:53:50
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'ONCE'	System	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 13:52:15

US3712035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:40:44

US3712035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:40:44

US3712035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '08:47'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:40:44

US3712035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '10 Sep 2020 08:47'	System	10 Sep 2020 16:40:44

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:22:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '08:50'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '10 Sep 2020 08:50'	System	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:18:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:18:34
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:18:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:18:34
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '08:50'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered empty.	System	15 Feb 2021 20:18:34
User entered '10 Sep 2020 08:50'	System	10 Sep 2020 16:41:02

US3712035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:52:48

US3712035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	10 Sep 2020 13:52:48

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:25:26', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e92ee53d-decf-49c6-9191-54ba0ca64648' User entered 'Yes (Y)'	System	10 Sep 2020 14:26:22
	System	10 Sep 2020 14:26:22

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:26:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e92ee53d-decf-49c6-9191-54ba0ca64648' User entered '97.9'	System	10 Sep 2020 14:26:22
	System	10 Sep 2020 14:26:22

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:26:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e92ee53d-decf-49c6-9191-54ba0ca64648'	System	10 Sep 2020 14:26:22
User entered 'No (N)'	System	10 Sep 2020 14:26:22

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:26:19', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e92ee53d-decf-49c6-9191-54ba0ca64648' User entered '10 Sep 2020 10:26'	System	10 Sep 2020 14:26:22
	System	10 Sep 2020 14:26:22

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 10:04'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 12:34'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:10:57', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '51e15171-bbbf-419c-a051-948ddcee4ac3' User entered 'Yes (Y)'	System	11 Sep 2020 00:11:50
	System	11 Sep 2020 00:11:50

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:11:22', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '51e15171-bbbf-419c-a051-948ddcee4ac3' User entered '98.1'	System	11 Sep 2020 00:11:50
	System	11 Sep 2020 00:11:50

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:11:26', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '51e15171-bbbf-419c-a051-948ddcee4ac3'	System	11 Sep 2020 00:11:50
User entered 'No (N)'	System	11 Sep 2020 00:11:50

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:11:45', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '51e15171-bbbf-419c-a051-948ddcee4ac3' User entered '10 Sep 2020 20:11'	System	11 Sep 2020 00:11:50
	System	11 Sep 2020 00:11:50

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 2'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:40:41', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'f96b8784-850a-484b-9bec-3f019110f115'	System	12 Sep 2020 00:41:16
User entered 'Yes (Y)'	System	12 Sep 2020 00:41:16

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:40:57', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'f96b8784-850a-484b-9bec-3f019110f115' User entered '99.1'	System	12 Sep 2020 00:41:16
	System	12 Sep 2020 00:41:16

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:41:02', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'f96b8784-850a-484b-9bec-3f019110f115'	System	12 Sep 2020 00:41:16
User entered 'No (N)'	System	12 Sep 2020 00:41:16

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:41:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'f96b8784-850a-484b-9bec-3f019110f115'	System	12 Sep 2020 00:41:16
User entered '11 Sep 2020 20:41'	System	12 Sep 2020 00:41:16

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 3'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:38:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2cb8e07b-0fbc-47c2-a86b-c198a4ee3bfc' User entered 'Yes (Y)'	System	12 Sep 2020 23:38:29
	System	12 Sep 2020 23:38:29

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:38:14', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2cb8e07b-0fbc-47c2-a86b-c198a4ee3bfc' User entered '97.8'	System	12 Sep 2020 23:38:29
	System	12 Sep 2020 23:38:29

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:38:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2cb8e07b-0fbc-47c2-a86b-c198a4ee3bfc' User entered 'No (N)'	System	12 Sep 2020 23:38:29
	System	12 Sep 2020 23:38:29

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:38:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2cb8e07b-0fbc-47c2-a86b-c198a4ee3bfc' User entered '12 Sep 2020 19:38'	System	12 Sep 2020 23:38:29
	System	12 Sep 2020 23:38:29

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 4'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:23:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd55cfb3b-c96e-4be6-8a18-c858a44801ad' User entered 'Yes (Y)'	System	13 Sep 2020 22:23:26
	System	13 Sep 2020 22:23:26

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:23:08', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd55cfb3b-c96e-4be6-8a18-c858a44801ad' User entered '97.4'	System	13 Sep 2020 22:23:26
	System	13 Sep 2020 22:23:26

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:23:12', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd55cfb3b-c96e-4be6-8a18-c858a44801ad' User entered 'No (N)'	System	13 Sep 2020 22:23:26
	System	13 Sep 2020 22:23:26

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:23:21', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd55cfb3b-c96e-4be6-8a18-c858a44801ad' User entered '13 Sep 2020 18:23'	System	13 Sep 2020 22:23:26
	System	13 Sep 2020 22:23:26

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 5'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:49:59', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b37c0e6f-8197-4f3b-b828-a0e41bc5140a' User entered 'Yes (Y)'	System	14 Sep 2020 23:50:24
	System	14 Sep 2020 23:50:24

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:50:08', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b37c0e6f-8197-4f3b-b828-a0e41bc5140a' User entered '97.7'	System	14 Sep 2020 23:50:24
	System	14 Sep 2020 23:50:24

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:50:12', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b37c0e6f-8197-4f3b-b828-a0e41bc5140a' User entered 'No (N)'	System	14 Sep 2020 23:50:24
	System	14 Sep 2020 23:50:24

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:50:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b37c0e6f-8197-4f3b-b828-a0e41bc5140a' User entered '14 Sep 2020 19:50'	System	14 Sep 2020 23:50:24
	System	14 Sep 2020 23:50:24

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 6'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:32:57', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '299e7735-6930-4802-845d-4e3ef817de08' User entered 'Yes (Y)'	System	15 Sep 2020 23:33:18
	System	15 Sep 2020 23:33:18

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '299e7735-6930-4802-845d-4e3ef817de08' User entered '97.7'	System	15 Sep 2020 23:33:18
	System	15 Sep 2020 23:33:18

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:08', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '299e7735-6930-4802-845d-4e3ef817de08' User entered 'No (N)'	System	15 Sep 2020 23:33:18
	System	15 Sep 2020 23:33:18

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:15', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '299e7735-6930-4802-845d-4e3ef817de08' User entered '15 Sep 2020 19:33'	System	15 Sep 2020 23:33:18
	System	15 Sep 2020 23:33:18

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 7'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:33:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '61497e7c-5574-4514-959c-8b2ff03b3529' User entered 'Yes (Y)'	System	17 Sep 2020 00:33:23
	System	17 Sep 2020 00:33:23

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:33:10', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '61497e7c-5574-4514-959c-8b2ff03b3529' User entered '98.3'	System	17 Sep 2020 00:33:23
	System	17 Sep 2020 00:33:23

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:33:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '61497e7c-5574-4514-959c-8b2ff03b3529' User entered 'No (N)'	System	17 Sep 2020 00:33:23
	System	17 Sep 2020 00:33:23

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:33:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '61497e7c-5574-4514-959c-8b2ff03b3529' User entered '16 Sep 2020 20:33'	System	17 Sep 2020 00:33:23
	System	17 Sep 2020 00:33:23

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:27:31', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c9bbd0cb-ba09-470f-ae79-b52fa03d4b87'	System	10 Sep 2020 14:27:59
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 14:27:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:27:35', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c9bbd0cb-ba09-470f-ae79-b52fa03d4b87' User entered 'No (N)'	System	10 Sep 2020 14:27:59
	System	10 Sep 2020 14:27:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:27:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c9bbd0cb-ba09-470f-ae79-b52fa03d4b87' User entered 'No (N)'	System	10 Sep 2020 14:27:59
	System	10 Sep 2020 14:27:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:27:46', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c9bbd0cb-ba09-470f-ae79-b52fa03d4b87'	System	10 Sep 2020 14:27:59
User entered 'None (1)'	System	10 Sep 2020 14:27:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:27:55', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c9bbd0cb-ba09-470f-ae79-b52fa03d4b87' User entered '10 Sep 2020 10:27'	System	10 Sep 2020 14:27:59
	System	10 Sep 2020 14:27:59

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 10:04'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 12:34'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:14:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '92bfd2f3-ea5c-42af-99fd-373a0ce57ea7'	System	11 Sep 2020 00:15:06
User entered 'None (1)'	System	11 Sep 2020 00:15:06

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:14:30', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '92bfd2f3-ea5c-42af-99fd-373a0ce57ea7'	System	11 Sep 2020 00:15:06
User entered 'No (N)'	System	11 Sep 2020 00:15:06

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:14:35', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '92bfd2f3-ea5c-42af-99fd-373a0ce57ea7'	System	11 Sep 2020 00:15:06
User entered 'No (N)'	System	11 Sep 2020 00:15:06

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:14:46', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '92bfd2f3-ea5c-42af-99fd-373a0ce57ea7'	System	11 Sep 2020 00:15:06
User entered 'None (1)'	System	11 Sep 2020 00:15:06

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:15:02', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '92bfd2f3-ea5c-42af-99fd-373a0ce57ea7'	System	11 Sep 2020 00:15:06
User entered '10 Sep 2020 20:15'	System	11 Sep 2020 00:15:06

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 2'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:41:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0b910c0a-b10d-444c-bbc4-f10f323c9792'	System	12 Sep 2020 00:43:00
User entered 'None (1)'	System	12 Sep 2020 00:43:00

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:41:49', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0b910c0a-b10d-444c-bbc4-f10f323c9792'	System	12 Sep 2020 00:43:00
User entered 'No (N)'	System	12 Sep 2020 00:43:00

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:42:10', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0b910c0a-b10d-444c-bbc4-f10f323c9792'	System	12 Sep 2020 00:43:00
User entered 'No (N)'	System	12 Sep 2020 00:43:00

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:42:15', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0b910c0a-b10d-444c-bbc4-f10f323c9792'	System	12 Sep 2020 00:43:00
User entered 'None (1)'	System	12 Sep 2020 00:43:00

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:42:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0b910c0a-b10d-444c-bbc4-f10f323c9792' User entered '11 Sep 2020 20:42'	System	12 Sep 2020 00:43:00
	System	12 Sep 2020 00:43:00

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 3'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:38:42', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3f4443bc-49d1-4934-9121-ab843255a307'	System	12 Sep 2020 23:40:43
User entered 'None (1)'	System	12 Sep 2020 23:40:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:38:50', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3f4443bc-49d1-4934-9121-ab843255a307'	System	12 Sep 2020 23:40:43
User entered 'No (N)'	System	12 Sep 2020 23:40:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:40:14', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3f4443bc-49d1-4934-9121-ab843255a307'	System	12 Sep 2020 23:40:43
User entered 'No (N)'	System	12 Sep 2020 23:40:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:40:29', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3f4443bc-49d1-4934-9121-ab843255a307' User entered 'None (1)'	System	12 Sep 2020 23:40:43
	System	12 Sep 2020 23:40:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:40:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3f4443bc-49d1-4934-9121-ab843255a307'	System	12 Sep 2020 23:40:43
User entered '12 Sep 2020 19:40'	System	12 Sep 2020 23:40:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 4'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:23:33', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8815eefc-5747-42ea-8e61-e383ae6bdb68' User entered 'None (1)'	System	13 Sep 2020 22:24:43
	System	13 Sep 2020 22:24:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:24:28', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8815eefc-5747-42ea-8e61-e383ae6bdb68' User entered 'No (N)'	System	13 Sep 2020 22:24:43
	System	13 Sep 2020 22:24:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:24:31', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8815eefc-5747-42ea-8e61-e383ae6bdb68' User entered 'No (N)'	System	13 Sep 2020 22:24:43
	System	13 Sep 2020 22:24:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:24:35', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8815eefc-5747-42ea-8e61-e383ae6bdb68' User entered 'None (1)'	System	13 Sep 2020 22:24:43
	System	13 Sep 2020 22:24:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:24:42', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8815eefc-5747-42ea-8e61-e383ae6bdb68' User entered '13 Sep 2020 18:24'	System	13 Sep 2020 22:24:43
	System	13 Sep 2020 22:24:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 5'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:50:28', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '05798d83-d0c7-4cab-a66c-37d5f48f91b3'	System	14 Sep 2020 23:52:24
User entered 'None (1)'	System	14 Sep 2020 23:52:24

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:50:33', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '05798d83-d0c7-4cab-a66c-37d5f48f91b3' User entered 'No (N)'	System	14 Sep 2020 23:52:24
	System	14 Sep 2020 23:52:24

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:50:36', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '05798d83-d0c7-4cab-a66c-37d5f48f91b3' User entered 'No (N)'	System	14 Sep 2020 23:52:24
	System	14 Sep 2020 23:52:24

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:50:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '05798d83-d0c7-4cab-a66c-37d5f48f91b3'	System	14 Sep 2020 23:52:24
User entered 'None (1)'	System	14 Sep 2020 23:52:24

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:22', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '05798d83-d0c7-4cab-a66c-37d5f48f91b3' User entered '14 Sep 2020 19:52'	System	14 Sep 2020 23:52:24
	System	14 Sep 2020 23:52:24

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 6'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:25:21', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '39439648-9dd3-43f7-8ea8-35d39a4c35bf' User entered 'None (1)'	System	15 Sep 2020 23:25:56
	System	15 Sep 2020 23:25:56

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:25:25', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '39439648-9dd3-43f7-8ea8-35d39a4c35bf' User entered 'No (N)'	System	15 Sep 2020 23:25:56
	System	15 Sep 2020 23:25:56

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:25:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '39439648-9dd3-43f7-8ea8-35d39a4c35bf' User entered 'No (N)'	System	15 Sep 2020 23:25:56
	System	15 Sep 2020 23:25:56

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:25:31', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '39439648-9dd3-43f7-8ea8-35d39a4c35bf' User entered 'None (1)'	System	15 Sep 2020 23:25:56
	System	15 Sep 2020 23:25:56

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:25:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '39439648-9dd3-43f7-8ea8-35d39a4c35bf' User entered '15 Sep 2020 19:25'	System	15 Sep 2020 23:25:56
	System	15 Sep 2020 23:25:56

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 7'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:33:28', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2592438f-83f0-43b3-9466-9b5878e3241e' User entered 'None (1)'	System	17 Sep 2020 00:34:43
	System	17 Sep 2020 00:34:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2592438f-83f0-43b3-9466-9b5878e3241e' User entered 'No (N)'	System	17 Sep 2020 00:34:43
	System	17 Sep 2020 00:34:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2592438f-83f0-43b3-9466-9b5878e3241e' User entered 'No (N)'	System	17 Sep 2020 00:34:43
	System	17 Sep 2020 00:34:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2592438f-83f0-43b3-9466-9b5878e3241e' User entered 'None (1)'	System	17 Sep 2020 00:34:43
	System	17 Sep 2020 00:34:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2592438f-83f0-43b3-9466-9b5878e3241e' User entered '16 Sep 2020 20:34'	System	17 Sep 2020 00:34:43
	System	17 Sep 2020 00:34:43

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:28:28', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered 'None (0)'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:28:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered 'None (0)'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:28:43', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered 'None (0)'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:28:45', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered 'None (0)'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:28:48', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered 'None (0)'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:28:50', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered 'None (0)'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:28:58', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered 'No (N)'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T10:29:06', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1599e8c3-dc76-44a7-b1c9-a0fd7c66095d' User entered '10 Sep 2020 10:29'	System	10 Sep 2020 14:29:17
	System	10 Sep 2020 14:29:17

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 10:04'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 12:34'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:15:30', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered 'None (0)'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:15:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered 'None (0)'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:15:51', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered 'None (0)'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:16:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered 'None (0)'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:16:11', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered 'None (0)'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:16:25', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered 'None (0)'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:16:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered 'No (N)'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-10T20:16:58', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '94cd2aba-0bfc-4343-a06d-efc9692353c0' User entered '10 Sep 2020 20:16'	System	11 Sep 2020 00:17:00
	System	11 Sep 2020 00:17:00

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 2'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:42:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered 'None (0)'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:43:30', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered 'None (0)'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:43:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered 'None (0)'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:43:37', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered 'None (0)'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:43:42', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered 'None (0)'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:43:45', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered 'None (0)'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:43:49', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered 'No (N)'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-11T20:43:59', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '93cd17cb-4247-44a3-b1a5-3bd36ffa4628' User entered '11 Sep 2020 20:43'	System	12 Sep 2020 00:53:06
	System	12 Sep 2020 00:53:06

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 3'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:40:56', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7' User entered 'None (0)'	System	12 Sep 2020 23:41:28
	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:41:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7' User entered 'None (0)'	System	12 Sep 2020 23:41:28
	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:41:07', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7' User entered 'None (0)'	System	12 Sep 2020 23:41:28
	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:41:10', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7' User entered 'None (0)'	System	12 Sep 2020 23:41:28
	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:41:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7' User entered 'None (0)'	System	12 Sep 2020 23:41:28
	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:41:16', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7' User entered 'None (0)'	System	12 Sep 2020 23:41:28
	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:41:19', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7'	System	12 Sep 2020 23:41:28
User entered 'No (N)'	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-12T19:41:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9c50bca7-c0c1-49a7-aac5-b556e09240d7' User entered '12 Sep 2020 19:41'	System	12 Sep 2020 23:41:28
	System	12 Sep 2020 23:41:28

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 4'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:24:53', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400' User entered 'None (0)'	System	13 Sep 2020 22:25:31
	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:25:01', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400' User entered 'None (0)'	System	13 Sep 2020 22:25:31
	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:25:05', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400' User entered 'None (0)'	System	13 Sep 2020 22:25:31
	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:25:10', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400' User entered 'None (0)'	System	13 Sep 2020 22:25:31
	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:25:12', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400' User entered 'None (0)'	System	13 Sep 2020 22:25:31
	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:25:15', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400' User entered 'None (0)'	System	13 Sep 2020 22:25:31
	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:25:17', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400' User entered 'No (N)'	System	13 Sep 2020 22:25:31
	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-13T18:25:26', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '22d67ab6-9a7f-44fb-85c6-a8cfb0176400'	System	13 Sep 2020 22:25:31
User entered '13 Sep 2020 18:25'	System	13 Sep 2020 22:25:31

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 5'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered 'None (0)'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered 'None (0)'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:43', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered 'None (0)'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:47', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered 'None (0)'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:49', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered 'None (0)'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered 'None (0)'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:52:55', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered 'No (N)'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-14T19:53:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '6e4fbee8-44c5-4aff-8e0e-617ae0ce799f' User entered '14 Sep 2020 19:53'	System	14 Sep 2020 23:53:05
	System	14 Sep 2020 23:53:05

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 6'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered 'None (0)'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:29', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered 'None (0)'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered 'None (0)'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:36', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered 'None (0)'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered 'None (0)'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:33:43', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered 'None (0)'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:34:02', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered 'No (N)'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-15T19:34:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3adc44e9-0fc1-43f8-ae51-fec2a1e77738' User entered '15 Sep 2020 19:34'	System	15 Sep 2020 23:34:19
	System	15 Sep 2020 23:34:19

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 7'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:48', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085' User entered 'None (0)'	System	17 Sep 2020 00:35:18
	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:51', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085' User entered 'None (0)'	System	17 Sep 2020 00:35:18
	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:55', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085' User entered 'None (0)'	System	17 Sep 2020 00:35:18
	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:34:57', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085' User entered 'None (0)'	System	17 Sep 2020 00:35:18
	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:35:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085' User entered 'None (0)'	System	17 Sep 2020 00:35:18
	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:35:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085' User entered 'None (0)'	System	17 Sep 2020 00:35:18
	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:35:06', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085'	System	17 Sep 2020 00:35:18
User entered 'No (N)'	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-09-16T20:35:16', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1fef3de8-32c4-468d-863a-7deaafb0d085'	System	17 Sep 2020 00:35:18
User entered '16 Sep 2020 20:35'	System	17 Sep 2020 00:35:18

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:52:15

US3712035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:05:46

US3712035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:05:46

US3712035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:05:46

US3712035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:05:46

US3712035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:06:46

US3712035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	02 Oct 2020 15:06:46

US3712035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:07:26

US3712035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:07:26

US3712035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:07:26

US3712035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:07:26

US3712035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:08:09

US3712035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	02 Oct 2020 15:08:09

US3712035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:28:51

US3712035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:28:51

US3712035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:28:51

US3712035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:28:51

US3712035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:43

US3712035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	07 Oct 2020 13:52:43

US3712035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:54

US3712035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:54

US3712035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:52:54

US3712035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'VISIT2'	System	07 Oct 2020 13:52:54

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '08:51'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '07 Oct 2020 08:51'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '67'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'bpm'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '14'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'breaths/min'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '98'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '68'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '10:19'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '07 Oct 2020 10:19'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '61'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'bpm'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'breaths/min'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '117'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '74'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'mmHg'	System	07 Oct 2020 14:31:25

US3712035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:31:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '09:48'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '07 Oct 2020 09:48'	System	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	07 Oct 2020 13:53:50
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	07 Oct 2020 13:53:50
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	07 Oct 2020 13:53:17
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 13:53:17
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'ONCE'	System	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 13:53:08

US3712035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:42

US3712035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:42

US3712035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '09:06'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:42

US3712035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '07 Oct 2020 09:06'	System	07 Oct 2020 14:32:42

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:22:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '09:07'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '07 Oct 2020 09:07'	System	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:18:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:18:49
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:09:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:18:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:18:49
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '09:07'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered empty.	System	15 Feb 2021 20:18:49
User entered '07 Oct 2020 09:07'	System	07 Oct 2020 14:32:50

US3712035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:54:31

US3712035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	07 Oct 2020 13:54:31

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:21:17', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'de476d18-b8a8-48e2-9ea9-ed5af5f07428' User entered 'Yes (Y)'	System	07 Oct 2020 14:21:44
	System	07 Oct 2020 14:21:44

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:21:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'de476d18-b8a8-48e2-9ea9-ed5af5f07428' User entered '97.8'	System	07 Oct 2020 14:21:44
	System	07 Oct 2020 14:21:44

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:21:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'de476d18-b8a8-48e2-9ea9-ed5af5f07428'	System	07 Oct 2020 14:21:44
User entered 'No (N)'	System	07 Oct 2020 14:21:44

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:21:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'de476d18-b8a8-48e2-9ea9-ed5af5f07428' User entered '07 Oct 2020 10:21'	System	07 Oct 2020 14:21:44
	System	07 Oct 2020 14:21:44

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 10:08'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 12:38'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:06:21', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '07a7ac4b-18fb-4e8e-8a5b-6d0662b3c6b0' User entered 'Yes (Y)'	System	07 Oct 2020 23:06:45
	System	07 Oct 2020 23:06:45

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:06:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '07a7ac4b-18fb-4e8e-8a5b-6d0662b3c6b0' User entered '98.4'	System	07 Oct 2020 23:06:45
	System	07 Oct 2020 23:06:45

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:06:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '07a7ac4b-18fb-4e8e-8a5b-6d0662b3c6b0' User entered 'No (N)'	System	07 Oct 2020 23:06:45
	System	07 Oct 2020 23:06:45

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:06:43', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '07a7ac4b-18fb-4e8e-8a5b-6d0662b3c6b0' User entered '07 Oct 2020 19:06'	System	07 Oct 2020 23:06:45
	System	07 Oct 2020 23:06:45

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 13:33'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 2'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:40:48', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64a17325-cb3b-4e15-a671-bd4935e330ad' User entered 'Yes (Y)'	System	08 Oct 2020 20:41:42
	System	08 Oct 2020 20:41:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:40:55', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64a17325-cb3b-4e15-a671-bd4935e330ad' User entered '99.6'	System	08 Oct 2020 20:41:42
	System	08 Oct 2020 20:41:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:41:01', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64a17325-cb3b-4e15-a671-bd4935e330ad' User entered 'Yes (Y)'	System	08 Oct 2020 20:41:42
	System	08 Oct 2020 20:41:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
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 'added' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 05:56:36
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).	(b) (4), (b) (6)	12 Oct 2020 18:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:41:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64a17325-cb3b-4e15-a671-bd4935e330ad'	System	08 Oct 2020 20:41:42
User entered '1'	System	08 Oct 2020 20:41:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
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 'added' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 05:56:40
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).	(b) (4), (b) (6)	12 Oct 2020 18:46:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:41:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64a17325-cb3b-4e15-a671-bd4935e330ad' User entered '1'	System	08 Oct 2020 20:41:42
	System	08 Oct 2020 20:41:42
	System	08 Oct 2020 20:41:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:41:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64a17325-cb3b-4e15-a671-bd4935e330ad' User entered '08 Oct 2020 16:41'	System	08 Oct 2020 20:41:42
	System	08 Oct 2020 20:41:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 3'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:46:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '29c9873b-08e1-480c-8e1d-8bcf95e2e18a' User entered 'Yes (Y)'	System	10 Oct 2020 00:46:19
	System	10 Oct 2020 00:46:19

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:45:57', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '29c9873b-08e1-480c-8e1d-8bcf95e2e18a' User entered '99.7'	System	10 Oct 2020 00:46:19
	System	10 Oct 2020 00:46:19

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:46:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '29c9873b-08e1-480c-8e1d-8bcf95e2e18a' User entered 'No (N)'	System	10 Oct 2020 00:46:19
	System	10 Oct 2020 00:46:19

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:46:15', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '29c9873b-08e1-480c-8e1d-8bcf95e2e18a' User entered '09 Oct 2020 20:46'	System	10 Oct 2020 00:46:19
	System	10 Oct 2020 00:46:19

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 4'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:04:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '42e06431-4819-4114-99be-ed0672379dcb' User entered 'Yes (Y)'	System	11 Oct 2020 00:04:39
	System	11 Oct 2020 00:04:39

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:04:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '42e06431-4819-4114-99be-ed0672379dcb' User entered '98.8'	System	11 Oct 2020 00:04:39
	System	11 Oct 2020 00:04:39

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:04:31', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '42e06431-4819-4114-99be-ed0672379dcb'	System	11 Oct 2020 00:04:39
User entered 'No (N)'	System	11 Oct 2020 00:04:39

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:04:37', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '42e06431-4819-4114-99be-ed0672379dcb' User entered '10 Oct 2020 20:04'	System	11 Oct 2020 00:04:39
	System	11 Oct 2020 00:04:39

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 5'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:19:31', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '14dd378a-cac9-43bf-a253-56a08fd2ed61' User entered 'Yes (Y)'	System	11 Oct 2020 23:22:21
	System	11 Oct 2020 23:22:21

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:22:07', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '14dd378a-cac9-43bf-a253-56a08fd2ed61' User entered '98.3'	System	11 Oct 2020 23:22:21
	System	11 Oct 2020 23:22:21

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:22:10', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '14dd378a-cac9-43bf-a253-56a08fd2ed61' User entered 'No (N)'	System	11 Oct 2020 23:22:21
	System	11 Oct 2020 23:22:21

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:22:17', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '14dd378a-cac9-43bf-a253-56a08fd2ed61' User entered '11 Oct 2020 19:22'	System	11 Oct 2020 23:22:21
	System	11 Oct 2020 23:22:21

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 6'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:31:53', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '89b8b34d-a7b1-49c3-83af-0172823cc855' User entered 'Yes (Y)'	System	13 Oct 2020 01:38:42
	System	13 Oct 2020 01:38:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:38:30', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '89b8b34d-a7b1-49c3-83af-0172823cc855' User entered '99.3'	System	13 Oct 2020 01:38:42
	System	13 Oct 2020 01:38:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:38:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '89b8b34d-a7b1-49c3-83af-0172823cc855'	System	13 Oct 2020 01:38:42
User entered 'No (N)'	System	13 Oct 2020 01:38:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:38:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '89b8b34d-a7b1-49c3-83af-0172823cc855'	System	13 Oct 2020 01:38:42
User entered '12 Oct 2020 21:38'	System	13 Oct 2020 01:38:42

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 7'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:43:58', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8dfd3e6a-7dce-4bdb-b934-3d47e0fb6129' User entered 'Yes (Y)'	System	14 Oct 2020 00:44:17
	System	14 Oct 2020 00:44:17

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:44:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8dfd3e6a-7dce-4bdb-b934-3d47e0fb6129' User entered '98.7'	System	14 Oct 2020 00:44:17
	System	14 Oct 2020 00:44:17

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:44:08', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8dfd3e6a-7dce-4bdb-b934-3d47e0fb6129' User entered 'No (N)'	System	14 Oct 2020 00:44:17
	System	14 Oct 2020 00:44:17

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:44:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8dfd3e6a-7dce-4bdb-b934-3d47e0fb6129' User entered '13 Oct 2020 20:44'	System	14 Oct 2020 00:44:17
	System	14 Oct 2020 00:44:17

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:22:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4f6d7556-694c-4b0a-8643-ca9cf9dc4247'	System	07 Oct 2020 14:22:46
User entered 'None (1)'	System	07 Oct 2020 14:22:46

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:22:17', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4f6d7556-694c-4b0a-8643-ca9cf9dc4247' User entered 'No (N)'	System	07 Oct 2020 14:22:46
	System	07 Oct 2020 14:22:46

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:22:23', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4f6d7556-694c-4b0a-8643-ca9cf9dc4247' User entered 'No (N)'	System	07 Oct 2020 14:22:46
	System	07 Oct 2020 14:22:46

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:22:33', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4f6d7556-694c-4b0a-8643-ca9cf9dc4247'	System	07 Oct 2020 14:22:46
User entered 'None (1)'	System	07 Oct 2020 14:22:46

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:22:41', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4f6d7556-694c-4b0a-8643-ca9cf9dc4247'	System	07 Oct 2020 14:22:46
User entered '07 Oct 2020 10:22'	System	07 Oct 2020 14:22:46

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 10:08'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 12:38'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:06:56', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0953a84f-581c-4ff4-b799-0e776aa2fe0d' User entered 'None (1)'	System	07 Oct 2020 23:19:26
	System	07 Oct 2020 23:19:26

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:07:02', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0953a84f-581c-4ff4-b799-0e776aa2fe0d' User entered 'No (N)'	System	07 Oct 2020 23:19:26
	System	07 Oct 2020 23:19:26

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:10:55', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0953a84f-581c-4ff4-b799-0e776aa2fe0d' User entered 'Yes (Y)'	System	07 Oct 2020 23:19:26
	System	07 Oct 2020 23:19:26

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:18:46', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0953a84f-581c-4ff4-b799-0e776aa2fe0d' User entered '250'	System	07 Oct 2020 23:19:26
	System	07 Oct 2020 23:19:26

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:10:06', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0953a84f-581c-4ff4-b799-0e776aa2fe0d' User entered 'None (1)'	System	07 Oct 2020 23:19:26
	System	07 Oct 2020 23:19:26

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0953a84f-581c-4ff4-b799-0e776aa2fe0d' User entered '07 Oct 2020 19:19'	System	07 Oct 2020 23:19:26
	System	07 Oct 2020 23:19:26

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 13:33'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 2'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:42:14', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '63967167-3d4e-4634-b92c-13de532a03a8'	System	08 Oct 2020 20:43:56
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 20:43:56

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:42:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '63967167-3d4e-4634-b92c-13de532a03a8' User entered 'Yes (Y)'	System	08 Oct 2020 20:43:56
	System	08 Oct 2020 20:43:56

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:42:28', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '63967167-3d4e-4634-b92c-13de532a03a8' User entered '650'	System	08 Oct 2020 20:43:56
	System	08 Oct 2020 20:43:56

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:42:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '63967167-3d4e-4634-b92c-13de532a03a8' User entered 'Yes (Y)'	System	08 Oct 2020 20:43:56
	System	08 Oct 2020 20:43:56

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:43:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '63967167-3d4e-4634-b92c-13de532a03a8' User entered '650'	System	08 Oct 2020 20:43:56
	System	08 Oct 2020 20:43:56

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:43:17', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '63967167-3d4e-4634-b92c-13de532a03a8' User entered 'None (1)'	System	08 Oct 2020 20:43:56
	System	08 Oct 2020 20:43:56

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:43:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '63967167-3d4e-4634-b92c-13de532a03a8' User entered '08 Oct 2020 16:43'	System	08 Oct 2020 20:43:56
	System	08 Oct 2020 20:43:56

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 3'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:49:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '34e291fd-9564-4af1-9c10-fdd51b72572f' User entered 'None (1)'	System	10 Oct 2020 00:53:37
	System	10 Oct 2020 00:53:37

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:49:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '34e291fd-9564-4af1-9c10-fdd51b72572f' User entered 'Yes (Y)'	System	10 Oct 2020 00:53:37
	System	10 Oct 2020 00:53:37

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:51:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '34e291fd-9564-4af1-9c10-fdd51b72572f' User entered '900'	System	10 Oct 2020 00:53:37
	System	10 Oct 2020 00:53:37

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:51:35', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '34e291fd-9564-4af1-9c10-fdd51b72572f' User entered 'Yes (Y)'	System	10 Oct 2020 00:53:37
	System	10 Oct 2020 00:53:37

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:53:15', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '34e291fd-9564-4af1-9c10-fdd51b72572f' User entered '900'	System	10 Oct 2020 00:53:37
	System	10 Oct 2020 00:53:37

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:53:22', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '34e291fd-9564-4af1-9c10-fdd51b72572f' User entered 'None (1)'	System	10 Oct 2020 00:53:37
	System	10 Oct 2020 00:53:37

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:53:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '34e291fd-9564-4af1-9c10-fdd51b72572f' User entered '09 Oct 2020 20:53'	System	10 Oct 2020 00:53:37
	System	10 Oct 2020 00:53:37

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 4'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:05:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd87ed89d-6502-4f5a-86c3-0f1530f45b14' User entered 'None (1)'	System	11 Oct 2020 00:07:13
	System	11 Oct 2020 00:07:13

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:05:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd87ed89d-6502-4f5a-86c3-0f1530f45b14' User entered 'Yes (Y)'	System	11 Oct 2020 00:07:13
	System	11 Oct 2020 00:07:13

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:05:58', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd87ed89d-6502-4f5a-86c3-0f1530f45b14' User entered '90'	System	11 Oct 2020 00:07:13
	System	11 Oct 2020 00:07:13

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:06:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd87ed89d-6502-4f5a-86c3-0f1530f45b14' User entered 'Yes (Y)'	System	11 Oct 2020 00:07:13
	System	11 Oct 2020 00:07:13

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:06:38', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd87ed89d-6502-4f5a-86c3-0f1530f45b14' User entered '80'	System	11 Oct 2020 00:07:13
	System	11 Oct 2020 00:07:13

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:06:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd87ed89d-6502-4f5a-86c3-0f1530f45b14' User entered 'None (1)'	System	11 Oct 2020 00:07:13
	System	11 Oct 2020 00:07:13

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:07:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd87ed89d-6502-4f5a-86c3-0f1530f45b14' User entered '10 Oct 2020 20:07'	System	11 Oct 2020 00:07:13
	System	11 Oct 2020 00:07:13

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 5'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:23:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c5b842e6-31d6-478b-af27-2d45be9bc92e' User entered 'None (1)'	System	11 Oct 2020 23:24:21
	System	11 Oct 2020 23:24:21

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:23:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c5b842e6-31d6-478b-af27-2d45be9bc92e' User entered 'Yes (Y)'	System	11 Oct 2020 23:24:21
	System	11 Oct 2020 23:24:21

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:23:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c5b842e6-31d6-478b-af27-2d45be9bc92e' User entered '60'	System	11 Oct 2020 23:24:21
	System	11 Oct 2020 23:24:21

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:23:49', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c5b842e6-31d6-478b-af27-2d45be9bc92e' User entered 'Yes (Y)'	System	11 Oct 2020 23:24:21
	System	11 Oct 2020 23:24:21

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:23:57', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c5b842e6-31d6-478b-af27-2d45be9bc92e' User entered '40'	System	11 Oct 2020 23:24:21
	System	11 Oct 2020 23:24:21

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:24:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c5b842e6-31d6-478b-af27-2d45be9bc92e' User entered 'None (1)'	System	11 Oct 2020 23:24:21
	System	11 Oct 2020 23:24:21

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:24:19', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c5b842e6-31d6-478b-af27-2d45be9bc92e' User entered '11 Oct 2020 19:24'	System	11 Oct 2020 23:24:21
	System	11 Oct 2020 23:24:21

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 6'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:39:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '53651a30-05ee-4a90-82d3-5cbcfb55b079' User entered 'None (1)'	System	13 Oct 2020 01:41:11
	System	13 Oct 2020 01:41:11

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:39:10', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '53651a30-05ee-4a90-82d3-5cbcfb55b079'	System	13 Oct 2020 01:41:11
User entered 'Yes (Y)'	System	13 Oct 2020 01:41:11

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

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)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:39:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '53651a30-05ee-4a90-82d3-5cbcfb55b079' User entered '25'	System	13 Oct 2020 01:41:11
	System	13 Oct 2020 01:41:11

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:40:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '53651a30-05ee-4a90-82d3-5cbcfb55b079'	System	13 Oct 2020 01:41:11
User entered 'No (N)'	System	13 Oct 2020 01:41:11

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:40:59', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '53651a30-05ee-4a90-82d3-5cbcfb55b079' User entered 'None (1)'	System	13 Oct 2020 01:41:11
	System	13 Oct 2020 01:41:11

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '53651a30-05ee-4a90-82d3-5cbcfb55b079' User entered '12 Oct 2020 21:41'	System	13 Oct 2020 01:41:11
	System	13 Oct 2020 01:41:11

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 7'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:44:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '52a37014-828d-492a-a91c-c3df0b651f17' User entered 'None (1)'	System	14 Oct 2020 00:45:34
	System	14 Oct 2020 00:45:34

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '52a37014-828d-492a-a91c-c3df0b651f17'	System	14 Oct 2020 00:45:34
User entered 'No (N)'	System	14 Oct 2020 00:45:34

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:17', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '52a37014-828d-492a-a91c-c3df0b651f17' User entered 'No (N)'	System	14 Oct 2020 00:45:34
	System	14 Oct 2020 00:45:34

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:21', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '52a37014-828d-492a-a91c-c3df0b651f17'	System	14 Oct 2020 00:45:34
User entered 'None (1)'	System	14 Oct 2020 00:45:34

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:26', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '52a37014-828d-492a-a91c-c3df0b651f17'	System	14 Oct 2020 00:45:34
User entered '13 Oct 2020 20:45'	System	14 Oct 2020 00:45:34

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:22:55', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered 'None (0)'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:22:59', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered 'None (0)'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:23:02', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered 'None (0)'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:23:06', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered 'None (0)'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:23:08', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered 'None (0)'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:23:10', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered 'None (0)'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:23:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered 'No (N)'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T10:23:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '49a35305-8077-462c-ae99-d16cebca4636' User entered '07 Oct 2020 10:23'	System	07 Oct 2020 14:23:42
	System	07 Oct 2020 14:23:42

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 10:08'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 12:38'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered 'None (0)'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:37', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered 'None (0)'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered 'None (0)'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:43', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered 'None (0)'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:45', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered 'None (0)'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:48', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered 'None (0)'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:19:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered 'No (N)'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-07T19:20:01', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '64ebee86-aad4-490f-a4b4-4b99d587f724' User entered '07 Oct 2020 19:20'	System	07 Oct 2020 23:20:07
	System	07 Oct 2020 23:20:07

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '07 Oct 2020 13:33'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 2'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:44:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a' User entered 'None (0)'	System	08 Oct 2020 20:46:54
	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:45:16', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a'	System	08 Oct 2020 20:46:54
User entered 'Some interference with activity (2)'	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:45:35', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a' User entered 'No interference with activity (1)'	System	08 Oct 2020 20:46:54
	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:45:46', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a'	System	08 Oct 2020 20:46:54
User entered 'No interference with activity (1)'	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:45:51', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a' User entered 'None (0)'	System	08 Oct 2020 20:46:54
	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:46:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a'	System	08 Oct 2020 20:46:54
User entered 'Some interference with activity not requiring medical attention (2)'	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:46:11', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a' User entered 'No (N)'	System	08 Oct 2020 20:46:54
	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-08T16:46:51', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '294d0269-2738-48ac-a82a-ad0088f2a11a' User entered '08 Oct 2020 16:46'	System	08 Oct 2020 20:46:54
	System	08 Oct 2020 20:46:54

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 3'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:54:30', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0' User entered 'None (0)'	System	10 Oct 2020 00:56:13
	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:54:37', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0'	System	10 Oct 2020 00:56:13
User entered 'No interference with activity (1)'	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:55:02', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0'	System	10 Oct 2020 00:56:13
User entered 'No interference with activity (1)'	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:55:05', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0'	System	10 Oct 2020 00:56:13
User entered 'No interference with activity (1)'	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:55:08', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0' User entered 'None (0)'	System	10 Oct 2020 00:56:13
	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:55:17', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0' User entered 'None (0)'	System	10 Oct 2020 00:56:13
	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:56:06', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0' User entered 'No (N)'	System	10 Oct 2020 00:56:13
	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-09T20:56:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '3cbdc105-074d-42c8-b592-2a5cb0033ed0' User entered '09 Oct 2020 20:56'	System	10 Oct 2020 00:56:13
	System	10 Oct 2020 00:56:13

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 4'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:07:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b' User entered 'None (0)'	System	11 Oct 2020 00:08:20
	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:07:42', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b' User entered 'None (0)'	System	11 Oct 2020 00:08:20
	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:07:53', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b' User entered 'None (0)'	System	11 Oct 2020 00:08:20
	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:07:56', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b' User entered 'None (0)'	System	11 Oct 2020 00:08:20
	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:07:59', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b' User entered 'None (0)'	System	11 Oct 2020 00:08:20
	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:08:04', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b'	System	11 Oct 2020 00:08:20
User entered 'No interference with activity (1)'	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:08:07', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b' User entered 'No (N)'	System	11 Oct 2020 00:08:20
	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-10T20:08:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '98d5e1ca-3b61-4b2f-876f-33aa37e67a3b' User entered '10 Oct 2020 20:08'	System	11 Oct 2020 00:08:20
	System	11 Oct 2020 00:08:20

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 5'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:24:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered 'None (0)'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:24:29', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered 'None (0)'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:24:37', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered 'None (0)'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:24:48', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered 'None (0)'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:24:52', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered 'None (0)'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:25:07', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered 'None (0)'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:25:11', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered 'No (N)'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-11T19:25:19', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '88f84c3a-2565-4cbe-8cff-66c28f33644c' User entered '11 Oct 2020 19:25'	System	11 Oct 2020 23:25:24
	System	11 Oct 2020 23:25:24

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 6'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:16', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered 'None (0)'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered 'None (0)'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:27', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered 'None (0)'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered 'None (0)'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered 'None (0)'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered 'None (0)'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:46', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered 'No (N)'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-12T21:41:55', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '794c5636-1049-4168-9152-ab0c151e6a6e' User entered '12 Oct 2020 21:41'	System	13 Oct 2020 01:41:58
	System	13 Oct 2020 01:41:58

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	07 Oct 2020 13:53:08
User entered 'Day 7'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc6d66f43' User entered 'None (0)'	System	14 Oct 2020 00:46:14
	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:43', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc6d66f43' User entered 'None (0)'	System	14 Oct 2020 00:46:14
	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:45', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc6d66f43' User entered 'None (0)'	System	14 Oct 2020 00:46:14
	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:48', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc6d66f43' User entered 'None (0)'	System	14 Oct 2020 00:46:14
	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:51', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc6d66f43' User entered 'None (0)'	System	14 Oct 2020 00:46:14
	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:45:54', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc6d66f43' User entered 'None (0)'	System	14 Oct 2020 00:46:14
	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:46:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc6d66f43' User entered 'No (N)'	System	14 Oct 2020 00:46:14
	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-10-13T20:46:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7f5a175f-08b6-44c5-8d8a-cbcfc66f43'	System	14 Oct 2020 00:46:14
User entered '13 Oct 2020 20:46'	System	14 Oct 2020 00:46:14

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 13:53:08

US3712035

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 13:53:08

US3712035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:09:11

US3712035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:09:11

US3712035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:09:11

US3712035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:09:11

US3712035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:10:08

US3712035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	19 Oct 2020 21:10:08

US3712035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:25:55

US3712035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:25:55

US3712035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:25:55

US3712035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:25:55

US3712035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:26:50

US3712035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	28 Oct 2020 15:26:50

US3712035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:10:09

US3712035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 10:10:10
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'confirmed entered in edc' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:37:58
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:27:44
User entered '28 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 14:10:09

US3712035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:10:09

US3712035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:10:09

US3712035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:10:11

US3712035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	09 Nov 2020 14:10:11

US3712035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:44:49

US3712035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:44:49

US3712035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:44:49

US3712035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'VISIT3'	System	01 Dec 2020 21:44:49

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered empty.	System	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered empty.	System	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered empty.	System	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered empty.	System	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered empty.	System	01 Dec 2020 21:45:25

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02

US3712035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02

US3712035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:32

US3712035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:32

US3712035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Thank you for the response. Please provide Accession number and tracking details for the sample dated 04NOV2020 for Visit 3 Day 57 in response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 08:54:50
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Thank you for the response. Please provide Accession number and tracking details for the sample dated 04NOV2020 for Visit 3 Day 57 in response to confirm with GCL records. Thank you.' answered with '1F606732291' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 20:55:55
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Thank you for the response. Please provide Accession number and tracking details for the sample dated 04NOV2020 for Visit 3 Day 57 in response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:54:00
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 04NOV2020. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:54:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 04NOV2020. Please clarify and update if appropriate.' answered with 'Requisition with the date 04NOV2020 in visit.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 13:26:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 04NOV2020. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:20:12

US3712035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 21:45:52

US3712035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:52

US3712035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered '09:05'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:52

US3712035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered '04 Nov 2020 09:05'	System	01 Dec 2020 21:45:52

US3712035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 21:57:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:56

US3712035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	01 Dec 2020 21:45:56

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 64'	System	10 Sep 2020 13:52:15

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-12T13:26:26', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e4f869ad-04db-4114-8460-91f3e4b8b34c' User entered 'No (N)'	System	12 Nov 2020 18:27:03
	System	12 Nov 2020 18:27:03

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-12T13:26:46', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e4f869ad-04db-4114-8460-91f3e4b8b34c'	System	12 Nov 2020 18:27:03
User entered 'No (N)'	System	12 Nov 2020 18:27:03

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-12T13:27:01', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e4f869ad-04db-4114-8460-91f3e4b8b34c' User entered '12 Nov 2020 13:27:01'	System	12 Nov 2020 18:27:03
	System	12 Nov 2020 18:27:03

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 13:52:15

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered 'Day 71'	System	10 Sep 2020 13:52:15

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-19T12:01:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'ae3d025d-fd82-4336-9009-bec640e7de76' User entered 'No (N)'	System	19 Nov 2020 17:01:58
	System	19 Nov 2020 17:01:58

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-19T12:01:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'ae3d025d-fd82-4336-9009-bec640e7de76'	System	19 Nov 2020 17:01:58
User entered 'No (N)'	System	19 Nov 2020 17:01:58

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-19T12:01:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'ae3d025d-fd82-4336-9009-bec640e7de76' User entered '19 Nov 2020 12:01:18'	System	19 Nov 2020 17:01:58
	System	19 Nov 2020 17:01:58

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 13:52:15

US3712035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:05
Data entry locked.	System	10 Sep 2020 13:52:15
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 13:52:15

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-24T07:50:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b0746197-933f-4420-a31c-3ceed6d62135'	System	24 Nov 2020 12:50:34
User entered 'No (N)'	System	24 Nov 2020 12:50:34

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-24T07:50:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b0746197-933f-4420-a31c-3ceed6d62135'	System	24 Nov 2020 12:50:34
User entered 'No (N)'	System	24 Nov 2020 12:50:34

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-24T07:50:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b0746197-933f-4420-a31c-3ceed6d62135' User entered '24 Nov 2020 07:50:32'	System	24 Nov 2020 12:50:34
	System	24 Nov 2020 12:50:34

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-28T10:19:08', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e58f1732-562b-49cf-840a-b1784d97ebbd' User entered 'No (N)'	System	28 Nov 2020 15:19:23
	System	28 Nov 2020 15:19:23

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-28T10:19:14', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e58f1732-562b-49cf-840a-b1784d97ebbd' User entered 'No (N)'	System	28 Nov 2020 15:19:23

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-11-28T10:19:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'e58f1732-562b-49cf-840a-b1784d97ebbd' User entered '28 Nov 2020 10:19:18'	System	28 Nov 2020 15:19:23
	System	28 Nov 2020 15:19:23

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-05T10:50:02', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '40d74299-7a82-4964-a4bf-1327b886f3fe' User entered 'No (N)'	System	05 Dec 2020 15:50:16
	System	05 Dec 2020 15:50:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-05T10:50:07', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '40d74299-7a82-4964-a4bf-1327b886f3fe' User entered 'No (N)'	System	05 Dec 2020 15:50:16
	System	05 Dec 2020 15:50:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-05T10:50:12', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '40d74299-7a82-4964-a4bf-1327b886f3fe' User entered '05 Dec 2020 10:50:12'	System	05 Dec 2020 15:50:16
	System	05 Dec 2020 15:50:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-14T12:01:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8ce7e0a1-5ec0-4848-b963-37dd6681fc54' User entered 'No (N)'	System	14 Dec 2020 17:02:41
	System	14 Dec 2020 17:02:41

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-14T12:02:29', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8ce7e0a1-5ec0-4848-b963-37dd6681fc54'	System	14 Dec 2020 17:02:41
User entered 'No (N)'	System	14 Dec 2020 17:02:41

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-14T12:02:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '8ce7e0a1-5ec0-4848-b963-37dd6681fc54' User entered '14 Dec 2020 12:02:39'	System	14 Dec 2020 17:02:41
	System	14 Dec 2020 17:02:41

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-19T09:04:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '72e6a5eb-b37c-492e-ab5c-ee2e9852a94c' User entered 'No (N)'	System	19 Dec 2020 14:05:00
	System	19 Dec 2020 14:05:00

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-19T09:03:31', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '72e6a5eb-b37c-492e-ab5c-ee2e9852a94c' User entered 'No (N)'	System	19 Dec 2020 14:05:00
	System	19 Dec 2020 14:05:00

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-19T09:04:58', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '72e6a5eb-b37c-492e-ab5c-ee2e9852a94c' User entered '19 Dec 2020 09:04:58'	System	19 Dec 2020 14:05:00
	System	19 Dec 2020 14:05:00

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-26T00:27:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '43bcfd1a-99c3-4c44-a595-16c85ad43658' User entered 'No (N)'	System	26 Dec 2020 05:27:38
	System	26 Dec 2020 05:27:38

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-26T00:27:28', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '43bcfd1a-99c3-4c44-a595-16c85ad43658' User entered 'No (N)'	System	26 Dec 2020 05:27:38

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2020-12-26T00:27:36', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '43bcfd1a-99c3-4c44-a595-16c85ad43658' User entered '26 Dec 2020 00:27:36'	System	26 Dec 2020 05:27:38
	System	26 Dec 2020 05:27:38

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-02T00:39:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '62499502-8ee6-4e95-b267-b14bcb1ac830'	System	02 Jan 2021 05:39:49
User entered 'No (N)'	System	02 Jan 2021 05:39:49

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-02T00:39:39', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '62499502-8ee6-4e95-b267-b14bcb1ac830'	System	02 Jan 2021 05:39:49
User entered 'No (N)'	System	02 Jan 2021 05:39:49

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-02T00:39:46', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '62499502-8ee6-4e95-b267-b14bcb1ac830'	System	02 Jan 2021 05:39:49
User entered '02 Jan 2021 00:39:46'	System	02 Jan 2021 05:39:49

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-09T00:13:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'dea7c2d0-d420-4e4f-b1fe-b6534cbb0605'	System	09 Jan 2021 05:13:50
User entered 'No (N)'	System	09 Jan 2021 05:13:50

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-09T00:13:40', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'dea7c2d0-d420-4e4f-b1fe-b6534cbb0605'	System	09 Jan 2021 05:13:50
User entered 'No (N)'	System	09 Jan 2021 05:13:50

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-09T00:13:48', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'dea7c2d0-d420-4e4f-b1fe-b6534cbb0605' User entered '09 Jan 2021 00:13:48'	System	09 Jan 2021 05:13:50
	System	09 Jan 2021 05:13:50

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-16T09:15:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0bdbfc81-297b-4df2-9e46-bbe14dc94019'	System	16 Jan 2021 14:15:19
User entered 'No (N)'	System	16 Jan 2021 14:15:19

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-16T09:15:09', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0bdbfc81-297b-4df2-9e46-bbe14dc94019'	System	16 Jan 2021 14:15:19
User entered 'No (N)'	System	16 Jan 2021 14:15:19

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-16T09:15:16', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '0bdbfc81-297b-4df2-9e46-bbe14dc94019' User entered '16 Jan 2021 09:15:16'	System	16 Jan 2021 14:15:19
	System	16 Jan 2021 14:15:19

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-23T00:05:03', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9f7a5a3f-0323-47e3-bded-1f0e56de9b88'	System	23 Jan 2021 05:05:55
User entered 'No (N)'	System	23 Jan 2021 05:05:55

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-23T00:05:13', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9f7a5a3f-0323-47e3-bded-1f0e56de9b88'	System	23 Jan 2021 05:05:55
User entered 'No (N)'	System	23 Jan 2021 05:05:55

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-23T00:05:20', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '9f7a5a3f-0323-47e3-bded-1f0e56de9b88' User entered '23 Jan 2021 00:05:20'	System	23 Jan 2021 05:05:55
	System	23 Jan 2021 05:05:55

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-30T14:53:24', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '276e4069-a369-4678-88b0-68a3e8f96d24' User entered 'No (N)'	System	30 Jan 2021 19:53:38
	System	30 Jan 2021 19:53:38

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-30T14:53:30', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '276e4069-a369-4678-88b0-68a3e8f96d24'	System	30 Jan 2021 19:53:38
User entered 'No (N)'	System	30 Jan 2021 19:53:38

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-01-30T14:53:34', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '276e4069-a369-4678-88b0-68a3e8f96d24' User entered '30 Jan 2021 14:53:34'	System	30 Jan 2021 19:53:38
	System	30 Jan 2021 19:53:38

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-06T08:17:18', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7a7d8c80-1335-4630-aa59-2cbe39d2b449' User entered 'No (N)'	System	06 Feb 2021 13:17:36
	System	06 Feb 2021 13:17:36

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-06T08:17:25', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7a7d8c80-1335-4630-aa59-2cbe39d2b449'	System	06 Feb 2021 13:17:36
User entered 'No (N)'	System	06 Feb 2021 13:17:36

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-06T08:17:30', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7a7d8c80-1335-4630-aa59-2cbe39d2b449'	System	06 Feb 2021 13:17:36
User entered '06 Feb 2021 08:17:30'	System	06 Feb 2021 13:17:36

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-13T12:56:22', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b1e517b4-3c5a-40af-8dc2-f8462ae02bc2'	System	13 Feb 2021 17:56:36
User entered 'No (N)'	System	13 Feb 2021 17:56:36

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-13T12:56:26', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b1e517b4-3c5a-40af-8dc2-f8462ae02bc2' User entered 'No (N)'	System	13 Feb 2021 17:56:36

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-13T12:56:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'b1e517b4-3c5a-40af-8dc2-f8462ae02bc2'	System	13 Feb 2021 17:56:36
User entered '13 Feb 2021 12:56:32'	System	13 Feb 2021 17:56:36

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-20T00:01:32', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '80efc08d-afd8-4b4a-ae2c-7090f016419a'	System	20 Feb 2021 05:04:01
User entered 'No (N)'	System	20 Feb 2021 05:04:01

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-20T00:01:38', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '80efc08d-afd8-4b4a-ae2c-7090f016419a' User entered 'No (N)'	System	20 Feb 2021 05:04:01

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-20T00:01:42', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '80efc08d-afd8-4b4a-ae2c-7090f016419a' User entered '20 Feb 2021 00:01:42'	System	20 Feb 2021 05:04:01
	System	20 Feb 2021 05:04:01

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-27T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'a9b5a9aa-1413-43f4-8c7d-0f2b7230fbe0'	System	27 Feb 2021 05:06:48
User entered 'No (N)'	System	27 Feb 2021 05:06:48

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-27T00:03:53-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'a9b5a9aa-1413-43f4-8c7d-0f2b7230fbe0' User entered 'No (N)'	System	27 Feb 2021 05:06:48
	System	27 Feb 2021 05:06:48

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-27T00:04:02-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'a9b5a9aa-1413-43f4-8c7d-0f2b7230fbe0' User entered '27 Feb 2021 05:04:02'	System	27 Feb 2021 05:06:48
	System	27 Feb 2021 05:06:48

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-06T09:41:22-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c18dfe35-e282-4ab5-83dd-fb0854e82865'	System	06 Mar 2021 14:42:04
User entered 'No (N)'	System	06 Mar 2021 14:42:04

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-06T09:41:52-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c18dfe35-e282-4ab5-83dd-fb0854e82865'	System	06 Mar 2021 14:42:04
User entered 'No (N)'	System	06 Mar 2021 14:42:04

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-06T09:42:01-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'c18dfe35-e282-4ab5-83dd-fb0854e82865'	System	06 Mar 2021 14:42:04
User entered '06 Mar 2021 09:42:01'	System	06 Mar 2021 14:42:04

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-13T00:02:54-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '746272c0-5a4a-463f-9c01-1ca355eda50f'	System	13 Mar 2021 05:05:07
User entered 'No (N)'	System	13 Mar 2021 05:05:07

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-13T00:02:58-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '746272c0-5a4a-463f-9c01-1ca355eda50f'	System	13 Mar 2021 05:05:07
User entered 'No (N)'	System	13 Mar 2021 05:05:07

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-13T00:03:03-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '746272c0-5a4a-463f-9c01-1ca355eda50f' User entered '13 Mar 2021 00:03:03'	System	13 Mar 2021 05:05:07
	System	13 Mar 2021 05:05:07

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-20T00:29:00-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '063303e0-f1e0-4f2b-aeac-df5f732babf8'	System	20 Mar 2021 04:29:14
User entered 'No (N)'	System	20 Mar 2021 04:29:14

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-20T00:29:06-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '063303e0-f1e0-4f2b-aeac-df5f732babf8'	System	20 Mar 2021 04:29:14
User entered 'No (N)'	System	20 Mar 2021 04:29:14

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-20T00:29:10-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '063303e0-f1e0-4f2b-aeac-df5f732babf8'	System	20 Mar 2021 04:29:14
User entered '20 Mar 2021 00:29:10'	System	20 Mar 2021 04:29:14

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-27T00:06:53-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2d05d8a8-5cab-4834-8deb-7529f67deea9'	System	27 Mar 2021 04:13:16
User entered 'No (N)'	System	27 Mar 2021 04:13:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-27T00:06:58-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2d05d8a8-5cab-4834-8deb-7529f67deea9'	System	27 Mar 2021 04:13:16
User entered 'No (N)'	System	27 Mar 2021 04:13:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-03-27T00:07:05-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '2d05d8a8-5cab-4834-8deb-7529f67deea9' User entered '27 Mar 2021 00:07:05'	System	27 Mar 2021 04:13:16
	System	27 Mar 2021 04:13:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-03T10:05:57-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4eb080dd-e4e2-49c0-8289-b512d6d8f234'	System	03 Apr 2021 14:06:10
User entered 'No (N)'	System	03 Apr 2021 14:06:10

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-03T10:06:01-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4eb080dd-e4e2-49c0-8289-b512d6d8f234'	System	03 Apr 2021 14:06:10
User entered 'No (N)'	System	03 Apr 2021 14:06:10

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-03T10:06:07-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '4eb080dd-e4e2-49c0-8289-b512d6d8f234'	System	03 Apr 2021 14:06:10
User entered '03 Apr 2021 10:06:07'	System	03 Apr 2021 14:06:10

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-10T00:05:47-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1063afb1-93ae-48e8-8db4-2d6b30a8745b' User entered 'No (N)'	System	10 Apr 2021 04:07:58
	System	10 Apr 2021 04:07:58

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-10T00:05:51-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1063afb1-93ae-48e8-8db4-2d6b30a8745b' User entered 'No (N)'	System	10 Apr 2021 04:07:58
	System	10 Apr 2021 04:07:58

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-10T00:05:55-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '1063afb1-93ae-48e8-8db4-2d6b30a8745b' User entered '10 Apr 2021 00:05:55'	System	10 Apr 2021 04:07:58
	System	10 Apr 2021 04:07:58

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-17T00:03:54-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd95d3d7c-3a19-4e3a-9b94-e7f07adb0e9b' User entered 'Yes (Y)'	System	17 Apr 2021 04:06:24
	System	17 Apr 2021 04:06:24

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-17T00:03:57-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd95d3d7c-3a19-4e3a-9b94-e7f07adb0e9b'	System	17 Apr 2021 04:06:24
User entered 'No (N)'	System	17 Apr 2021 04:06:24

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-17T00:04:01-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd95d3d7c-3a19-4e3a-9b94-e7f07adb0e9b' User entered 'No (N)'	System	17 Apr 2021 04:06:24
	System	17 Apr 2021 04:06:24

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-17T00:04:07-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd95d3d7c-3a19-4e3a-9b94-e7f07adb0e9b' User entered 'Yes (Y)'	System	17 Apr 2021 04:06:24
	System	17 Apr 2021 04:06:24

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-17T00:04:23-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd95d3d7c-3a19-4e3a-9b94-e7f07adb0e9b'	System	17 Apr 2021 04:06:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 04:06:24

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-17T00:04:38-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'd95d3d7c-3a19-4e3a-9b94-e7f07adb0e9b' User entered '17 Apr 2021 00:04:38'	System	17 Apr 2021 04:06:24
	System	17 Apr 2021 04:06:24

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-24T07:41:29-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '5d3cc986-8c72-48fe-baeb-33ca8da58a4b'	System	24 Apr 2021 11:41:41
User entered 'No (N)'	System	24 Apr 2021 11:41:41

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-24T07:41:33-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '5d3cc986-8c72-48fe-baeb-33ca8da58a4b'	System	24 Apr 2021 11:41:41
User entered 'No (N)'	System	24 Apr 2021 11:41:41

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-04-24T07:41:39-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '5d3cc986-8c72-48fe-baeb-33ca8da58a4b'	System	24 Apr 2021 11:41:41
User entered '24 Apr 2021 07:41:39'	System	24 Apr 2021 11:41:41

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-05-01T00:02:50-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7d3dfcaa-19d6-4af7-991f-6fb522176a40'	System	01 May 2021 04:56:16
User entered 'No (N)'	System	01 May 2021 04:56:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-05-01T00:02:55-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7d3dfcaa-19d6-4af7-991f-6fb522176a40'	System	01 May 2021 04:56:16
User entered 'No (N)'	System	01 May 2021 04:56:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-05-01T00:03:02-04:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: '7d3dfcaa-19d6-4af7-991f-6fb522176a40'	System	01 May 2021 04:56:16
User entered '01 May 2021 00:03:02'	System	01 May 2021 04:56:16

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:26:35

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 03:26:35

US3712035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:35
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 03:26:35

US3712035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:22:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-27T10:26:46-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'a3b98bc4-00f7-4aea-9934-8614b7dd61f9'	System	27 Feb 2021 15:27:00
User entered 'No (N)'	System	27 Feb 2021 15:27:00

US3712035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:22:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1F64C986-FD56-4F31-9AD9-2D2DE82D2163)', Time: '2021-02-27T10:26:57-05:00', User OID: 'PatientReportedOutcome (US3712035)', ODM File OID: 'a3b98bc4-00f7-4aea-9934-8614b7dd61f9' User entered '27 Feb 2021 15:26:57'	System	27 Feb 2021 15:27:00
	System	27 Feb 2021 15:27:00

US3712035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:01:46

US3712035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:01:46

US3712035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:01:46

US3712035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:01:46

US3712035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:28:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:01:48

US3712035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:55:02
User entered 'I'	System	04 Jan 2021 14:01:48

US3712035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 20:22:14

US3712035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered '05 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 20:22:14

US3712035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Jan 2021 20:22:14

US3712035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 20:22:14

US3712035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 20:22:16

US3712035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User entered 'I'	System	14 Jan 2021 20:22:16

US3712035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 17:32:31

US3712035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered '06 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 17:32:31

US3712035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 17:32:31

US3712035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 17:32:31

US3712035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 17:32:33

US3712035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User entered 'I'	System	22 Feb 2021 17:32:33

US3712035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 21:12:33

US3712035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered '05 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 21:12:33

US3712035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Mar 2021 21:12:33

US3712035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 21:12:33

US3712035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 21:12:36

US3712035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:41:47
User entered 'I'	System	10 Mar 2021 21:12:36

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:12

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:12

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:12

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 15:43:12

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:44:05
User entered '06 Jan 2021'	(b) (4), (b) (6)	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:13:04

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:13:04

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:22:58

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered empty.	System	25 Feb 2021 15:43:41

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:45:32

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:45:32

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '09:46'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:45:32

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '22 Feb 2021 09:46'	System	25 Feb 2021 15:45:32

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:45:43

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:45:43

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '09:47'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:45:43

US3712035

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:58

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:16:48
User entered '22 Feb 2021 09:47'	System	25 Feb 2021 15:45:43

US3712035

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:22:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:11
User signature succeeded.	William Smith (b) (4)	12 Mar 2021 22:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 19:35:34

US3712035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:13:15
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:01
User entered	System	17 Dec 2020 14:16:55
'USA-US068-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	17 Dec 2020 14:16:55

US3712035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please confirm the AE term "WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 17:14:36
Query 'Per DM CLR: Please confirm the AE term "WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'NONDISPLACED FRACTURE OF LEFT ACROMION PROCESS is in medical hisotry ' (Site from DM).	William Smith (b) (4)	04 Apr 2021 23:54:48
User opened query 'Per DM CLR: Please confirm the AE term "WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Shoulder fracture - version MedDRA\23.0.	(b) (4), (b) (6)	01 Apr 2021 15:10:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	(b) (4), (b) (6)	
Data point term sent to Coder DataPoint Un-verified.	(b) (4), (b) (6)	27 Mar 2021 01:58:30
	Coder Import (b) (4)	06 Mar 2021 12:38:00
	(b) (4)	
	Coder Import (b) (4)	06 Mar 2021 12:38:00
	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:45:19
	(b) (4), (b) (6)	04 Mar 2021 20:50:57
	(b) (4), (b) (6)	04 Mar 2021 20:50:34

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	04 Mar 2021 20:50:34
User entered 'worsening of left shoulder acromial fracture' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 20:50:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:13:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Shoulder fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 11:07:25
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 11:07:25
Data point term sent to Coder	System	16 Dec 2020 21:07:12
User entered 'acromial fracture, left shoulder'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:14:57
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:15:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:15:02
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User closed query 'PV Query: Please clarify onset of left shoulder pain. If pain started prior to X-ray on 22Oct2020, please provide approximate start date.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:35:41
Query 'PV Query: Please clarify onset of left shoulder pain. If pain started prior to X-ray on 22Oct2020, please provide approximate start date.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 20:50:47
User opened query 'PV Query: Please clarify onset of left shoulder pain. If pain started prior to X-ray on 22Oct2020, please provide approximate start date.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 20:38:04
User closed query 'Please confirm date that symptoms began to worsen for this subject's left shoulder pain. As the start date would be when it worsened that led to the surgery. And confirm if this is ongoing or fully resolved after the procedure.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:27:14
Query 'Please confirm date that symptoms began to worsen for this subject's left shoulder pain. As the start date would be when it worsened that led to the surgery. And confirm if this is ongoing or fully resolved after the procedure.' answered with 'start date of SAE is confirmed. Confirmed resolved post procedure ' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 21:20:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:31:32
User opened query 'Please confirm date that symptoms began to worsen for this subject's left shoulder pain. As the start date would be when it worsened that led to the surgery. And confirm if this is ongoing or fully resolved after the procedure.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:24:22
User entered '22 Oct 2020'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:31:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:24:24
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:24:25
User entered '23 Oct 2020'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:24:27
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 21:06:50

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 14:45:37
User closed query 'Please confirm, this appears this is moderate per a safety report in source. If confirmed, please update.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:45:36
Query 'Please confirm, this appears this is moderate per a safety report in source. If confirmed, please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:48:54
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 14:48:39
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 14:48:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:48:39
User opened query 'Please confirm, this appears this is moderate per a safety report in source. If confirmed, please update.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:27:51
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:24:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:24:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:31:37
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

US3712035

Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:31:38
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:31:56
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:31:57
User entered '22 Oct 2020'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:31:59
User entered '23 Oct 2020'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:32:01
User entered 'No (N)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:32:02
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:32:04
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

US3712035

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:32:05
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:32:06
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:32:10
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:32:11
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:02:30
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:32:13
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 12:57:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 12:57:14
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 18:48:22
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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None

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:38:38
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	05 Apr 2021 12:26:54
	William Smith (b) (4)	04 Apr 2021 23:54:48
User closed query 'PV Query: Please confirm ascorbic acid carbonyl iron (start date 01 Sep 2020) and cefazolin (start date 22 Oct 2012) were both treatment for reverse arthroplasty performed on 22 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 19:02:21
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 16:16:27
Query 'PV Query: Please confirm ascorbic acid carbonyl iron (start date 01 Sep 2020) and cefazolin (start date 22 Oct 2012) were both treatment for reverse arthroplasty performed on 22 Oct 2020.' answered with 'ascorbic acid started before so I updated indication. Cefazolin started after procedure on same day.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 16:01:01
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:58:49
User opened query 'PV Query: Please confirm ascorbic acid carbonyl iron (start date 01 Sep 2020) and cefazolin (start date 22 Oct 2012) were both treatment for reverse arthroplasty performed on 22 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:40:53

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:45:34
User closed query 'Per CDM: Please confirm no Concomitant Medication was given for this AE.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:42:28
Query 'Per CDM: Please confirm no Concomitant Medication was given for this AE.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:14:24
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 14:14:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 14:14:14
User opened query 'Per CDM: Please confirm no Concomitant Medication was given for this AE.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 21:23:05
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:38:39
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is DIAGNOSTIC and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:31:50
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is DIAGNOSTIC and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 20:07:30
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is DIAGNOSTIC and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:27:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:38:46
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 20:38:57
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User closed query 'PV Query: Please clarify medical history of 'Left Anterior Descending Artery'.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:02:27
Query 'PV Query: Please clarify medical history of 'Left Anterior Descending Artery'.' answered with 'updated in medical history ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 16:17:23
User opened query 'PV Query: Please clarify medical history of 'Left Anterior Descending Artery'.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:41:05
User closed query 'PV Query: Please clarify onset of left shoulder pain. If pain started prior to X-ray on 22Oct2020, please provide approximate start date.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 13:35:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:45:39
Query 'PV Query: Please clarify onset of left shoulder pain. If pain started prior to X-ray on 22Oct2020, please provide approximate start date.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 20:50:53
User closed query 'PV Query: Please add reported medical history of osteoarthritis on shoulders into medical history form in EDC.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 14:59:50
User closed query 'Per DM CLR: SAE Narrative = MRI OF ROTATOR CUFF. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:01:46
User closed query 'Per DM CLR: SAE Narrative = CT SCAN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:43:18
User closed query 'Per DM CLR: SAE Narrative = X-RAYS TAKEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:43:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = CT SCAN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:08:45
Query 'Per DM CLR: SAE Narrative = MRI OF ROTATOR CUFF. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:08:17
Query 'Per DM CLR: SAE Narrative = X-RAYS TAKEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:07:50
Query 'PV Query: Please add reported medical history of osteoarthritis on shoulders into medical history form in EDC.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 13:40:58
User closed query 'PV Query: Please clarify whether there was a fall, trauma, or injury prior to onset of left shoulder pain. If yes, please describe.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 13:48:24
User closed query 'PV Query: Subject tested negative for COVID-19. Please provide the date and type of test that was performed.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 13:48:09
Query 'PV Query: Please clarify whether there was a fall, trauma, or injury prior to onset of left shoulder pain. If yes, please describe.' answered with 'no indication ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:38:51
Query 'PV Query: Subject tested negative for COVID-19. Please provide the date and type of test that was performed.' answered with 'narrative updated' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:38:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED AT PHYSICIAN'S OFFICE WITH LEFT SHOULDER PAIN. X-RAYS TAKEN OF SHOULDER REVEALED A CHRONIC ACROMIAL FRACTURE. MRI OF ROTATOR CUFF WAS DONE SHOWING MARKED INFLAMMATORY CHANGE WITH THE JOINT. CT SCAN OF THE LEFT SHOULDER SHOWED SEVERE GLENOHUMERAL JOINT ARTHRITIS WITH THE UNUNITED ACROMIAL FRACTURE. SUBJECT HAS HISTORY WITH OSTEOARTHRITIS ON SHOULDERS STARTING IN 2013. SUBJECT WAS CONSULTED WITH RESULTS. SUBJECT WAS IN AGREEMENT TO PROCEED WITH REVERSE ARTHROPLASTY. SUBJECT WAS ADMITTED TO PARKWEST MEDICAL CENTER ON 22OCT2020 FOR PROCEDURE OF REVERSE ARTHROPLASTY. SUBJECT WAS DISCHARGED TO HOME ON 23OCT2020. SARS-COV-2 TESTING (Aptima® />SARS-CoV-2 Assay) WAS COMPLETED AT PARKWEST MEDICAL CENTER on 19OCT2020, RESULT WAS NEGATIVE.' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 16:33:19
User opened query 'PV Query: Please clarify onset of left shoulder pain. If pain started prior to X-ray on 22Oct2020, please provide approximate start date.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:30:22
User opened query 'PV Query: Please clarify whether there was a fall, trauma, or injury prior to onset of left shoulder pain. If yes, please describe.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:30:16
User opened query 'PV Query: Subject tested negative for COVID-19. Please provide the date and type of test that was performed.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:29:51
User opened query 'PV Query: Please add reported medical history of osteoarthritis on shoulders into medical history form in EDC.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:29:45
User opened query 'Per DM CLR: SAE Narrative = CT SCAN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:27:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = MRI OF ROTATOR CUFF. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:26:56
User opened query 'Per DM CLR: SAE Narrative = X-RAYS TAKEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:26:49
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 14:53:12
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).' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 14:53:10
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)	03 Feb 2021 14:53:08
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 20:03:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED AT PHYSICIAN'S OFFICE WITH LEFT SHOULDER PAIN. X-RAYS TAKEN OF SHOULDER REVEALED A CHRONIC ACROMIAL FRACTURE. MRI OF ROTATOR CUFF WAS DONE SHOWING MARKED INFLAMMATORY CHANGE WITH THE JOINT. CT SCAN OF THE LEFT SHOULDER SHOWED SEVERE GLENOHUMERAL JOINT ARTHRITIS WITH THE UNUNITED ACROMIAL FRACTURE. subject has history with osteoarthritis on shoulders starting in 2013. SUBJECT WAS CONSULTED WITH RESULTS. SUBJECT WAS IN AGREEMENT TO PROCEED WITH REVERSE ARTHROPLASTY. SUBJECT WAS ADMITTED TO PARKWEST MEDICAL CENTER ON 22OCT2020 FOR PROCEDURE OF REVERSE ARTHROPLASTY. SUBJECT WAS DISCHARGED TO HOME ON 23OCT2020. SARS-COV-2 TESTING WAS COMPLETED AT PARKWEST MEDICAL CENTER, RESULT WAS NEGATIVE.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 20:03:00
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).' answered with 'medication added to cc meds' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 20:00:48
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'There was no relevant labs' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 19:53:51
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)	02 Feb 2021 14:12:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Narrative](#)

Audit	User	Time (GMT)
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 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 21:24:17
	(b) (4), (b) (6)	01 Feb 2021 21:24:11
User entered 'SUBJECT PRESENTED AT PHYSICIAN'S OFFICE WITH LEFT SHOULDER PAIN. X-RAYS TAKEN OF SHOULDER REVEALED A CHRONIC ACROMIAL FRACTURE. MRI OF ROTATOR CUFF WAS DONE SHOWING MARKED INFLAMMATORY CHANGE WITH THE JOINT. CT SCAN OF THE LEFT SHOULDER SHOWED SEVERE GLENOHUMERAL JOINT ARTHRITIS WITH THE UNUNITED ACROMIAL FRACTURE. SUBJECT WAS CONSULTED WITH RESULTS. SUBJECT WAS IN AGREEMENT TO PROCEED WITH REVERSE ARTHROPLASTY. SUBJECT WAS ADMITTED TO PARKWEST MEDICAL CENTER ON 22OCT2020 FOR PROCEDURE OF REVERSE ARTHROPLASTY. SUBJECT WAS DISCHARGED TO HOME ON 23OCT2020. SARS-CoV-2 testing was completed at Parkwest medical center, result was negative.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:24:11
	(b) (4), (b) (6)	05 Jan 2021 20:39:05
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 18:49:17
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).' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 18:49:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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 18:48:33
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 18:48:07
User entered 'Subject presented at physician's office with left shoulder pain. X-rays taken of shoulder revealed a chronic acromial fracture. MRI of rotator cuff was done showing marked inflammatory change with the joint. CT scan of the left shoulder showed severe glenohumeral joint arthritis with the ununited acromial fracture. Subject was consulted with results. Subject was in agreement to proceed with reverse arthroplasty. Subject was admitted to Parkwest Medical Center on 22Oct2020 for procedure of reverse arthroplasty. Subject was discharged to home on 23Oct2020.'	(b) (4), (b) (6)	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Dec 2020 21:06:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:40:23
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:40:21
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:00:43
Data point term sent to Coder	System	05 Jan 2021 15:00:03
User entered 'mild anemia'	(b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:37
DataPoint Verified.	(b) (4)	21 Apr 2021 14:45:49
User closed query 'Please confirm, should this be yes, if this was a new diagnosis by a medical physician' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:45:47
Query 'Please confirm, should this be yes, if this was a new diagnosis by a medical physician' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:47:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 14:47:28
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 14:47:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:47:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User opened query 'Please confirm, should this be yes, if this was a new diagnosis by a medical physician' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:22:12
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

US3712035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

US3712035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

US3712035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

US3712035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

US3712035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:57
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:59:11

US3712035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Jan 2021 14:59:11

US3712035

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:47:28
User entered '0'	System	05 Jan 2021 14:59:11

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:22:58

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:11
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:50:07
User closed query 'Per CDM : In Diary Dose 2(1) - Temperature Day 2, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:14:40
Query 'Per CDM : In Diary Dose 2(1) - Temperature Day 2, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' answered with 'ConMed is recorded for 08OCT2020' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 19:33:57
User opened query 'Per CDM : In Diary Dose 2(1) - Temperature Day 2, Medication was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:19:10

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:53:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 16:21:43
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Sep 2020 16:21:43
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	10 Sep 2020 16:20:13
User entered 'rosuvastatin'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:53:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:25
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:13:55
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:31
User entered '5'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:54:33
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:54:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:54:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:54:54
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:54:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:54:58
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:54:59
User entered 'un Aug 2019'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:55:02
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:55:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:55:15
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:55:17
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:19:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 16:21:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 16:21:47
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 16:21:17
User entered 'fenofibrate'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '145'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 21:06:50
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 22:32:34
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.	(b) (4), (b) (6)	09 Oct 2020 17:09:43
' answered with 'updated' (Site from DM).		
User entered 'UN Aug 2019' reason for change:	(b) (4), (b) (6)	09 Oct 2020 17:09:34
Data Entry Error		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:25:48
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:20:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
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)	10 Sep 2020 16:22:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:22:43
Data point term sent to Coder	System	10 Sep 2020 16:22:19
User entered 'omeprazole'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Acid reflux'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '40'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2000'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:21:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE, PRODUCTSYNONYM: PROSCAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:22:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:22:43
Data point term sent to Coder	System	10 Sep 2020 16:22:20
User entered 'proscar'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Benign prostatic hyperplasia'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '5'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 21:06:50
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2000'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:22:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:23:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:23:54
Data point term sent to Coder	System	10 Sep 2020 16:23:21
User entered 'trazodone'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Insomnia'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '25'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 21:06:50
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2012'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:22:38

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:25:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:25:39
Data point term sent to Coder	System	10 Sep 2020 16:24:28
User entered 'escitalopram'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Anxiety'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '20'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 21:06:50
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2018'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:23:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:26:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:26:44
Data point term sent to Coder	System	10 Sep 2020 16:25:32
User entered 'famotidine'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '40'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2000'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:24:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:27:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:27:50
Data point term sent to Coder	System	10 Sep 2020 16:26:34
User entered 'vitamin D3'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 21:06:50
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:14:31
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 13:00:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 13:00:01
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:53:38
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'supplement'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 22:32:45
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:15:10
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:15:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:25:58
User entered '2'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:15:02
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:25:39
	(b) (4), (b) (6)	

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:25:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:28:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:28:42
Data point term sent to Coder	System	10 Sep 2020 16:27:37
User entered 'vitamin B complex'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 13:00:22
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'supplement'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:26:59

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:29:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:29:45
Data point term sent to Coder	System	10 Sep 2020 16:28:39
User entered 'zyrtec'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'seasonal allergic rhinitis'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '10'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'twice daily (BID)'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un Feb 2019'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:27:54

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:29:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:29:44
Data point term sent to Coder	System	10 Sep 2020 16:28:39
User entered 'glucosamine'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 13:00:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Supplement'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	05 Jan 2021 21:06:50
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un UNK 2000'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:28:27

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIQUINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:30:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:30:48
Data point term sent to Coder	System	10 Sep 2020 16:29:41
User entered 'ubiquinol'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 13:00:41
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'supplement'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un Dec 2019'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:29:03

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:31:41
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	10 Sep 2020 16:30:44 10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Cardiac prophylaxis'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '81'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un Aug 2019'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:34
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 19:59:39
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:58:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 19:58:36
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:32
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:39
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 19:58:36
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 19:58:36
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:29:57

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:31:41
Data point term sent to Coder	System	10 Sep 2020 16:30:44
User entered 'melatonin'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Insomnia'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '10'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'as needed (PRN)'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'un Jul 2020'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:30:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: ASCORBIC ACID; FERROUS FUMARATE, PRODUCTSYNONYM: VITRON C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:45:24
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 Oct 2020 23:45:24
Data point term sent to Coder	System	12 Oct 2020 18:44:40
User entered 'iron vitron c'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
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)	07 Jan 2021 07:17:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:06:50
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 'AE written ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 14:45:06
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 Dec 2020 05:52:54
User entered 'mild anemia'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '125'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 18:43:45

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
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)	12 Oct 2020 18:47:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 18:47:40
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 18:46:44
User entered 'Ibuprofen'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:00:46
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:06:50
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' answered with 'Was in 7 day diary window therefore does not need AE' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 14:44:54
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:51:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User entered 'Fever'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '400'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'as needed (PRN)'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:46:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:29:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:29:30
Data point term sent to Coder	System	05 Jan 2021 13:18:23
User entered 'aspirin'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'pre and post op blood clot prophylaxis '	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:35:32
User closed query 'Please confirm why this was changed from 81 to 325. Per source con med log, 81 is noted. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:35:16
Query 'Please confirm why this was changed from 81 to 325. Per source con med log, 81 is noted. ' answered with 'changed back ton 81' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:14:02
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 21:02:47
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 21:02:47
User opened query 'Please confirm why this was changed from 81 to 325. Per source con med log, 81 is noted. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:07:05
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 19:58:52
User entered '325' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 19:58:52
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '81'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:35:54
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:11
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 20:00:11
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '15 Oct 2020'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 13:18:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: ASCORBIC ACID; FERROUS FUMARATE, PRODUCTSYNONYM: VITRON C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:28:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:28:31
	(b) (4)	
Data point term sent to Coder	System	05 Jan 2021 13:19:24
User entered 'vitron-c plus iron'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'dietary supplement '	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '125/65'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '22 Oct 2020'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:06:50
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 13:19:01

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: RANITIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:12:51
Data point term sent to Coder	System	13 Apr 2021 12:09:12
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:08:45
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: RANITIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:40:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:40:17
User closed query 'Per DM CLR: Please review Name of Medication as it can not be verified. RANITIDINE and CIMETIDINE are two different non-combination generic names. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:25:38
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder	System	02 Apr 2021 12:04:42
Query 'Per DM CLR: Please review Name of Medication as it can not be verified. RANITIDINE and CIMETIDINE are two different non-combination generic names. Please review and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:04:30
User entered 'RANITIDINE' reason for change:	(b) (4), (b) (6)	02 Apr 2021 12:04:17
Data Entry Error		

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Apr 2021 16:13:41
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:13:34
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: RANITIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:14:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:14:24
User opened query 'Per DM CLR: Please review Name of Medication as it can not be verified. RANITIDINE and CIMETIDINE are two different non-combination generic names. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:42:36
Data point term sent to Coder	System	01 Mar 2021 14:16:38
User entered 'ranitidine (cimetidine)'	(b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:11:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:11:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:08:45
User entered 'PREVENTION OF Gastroesophageal reflux disease during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:08:45
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:13:34
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '200'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
	(b) (4), (b) (6)	
User closed query 'Please correct spelling of "as" ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:53:01
Query 'Please correct spelling of "as" ' answered with 'fixed ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:29:43
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:29:36
	(b) (4), (b) (6)	
User entered 'EVERY 12 HOURS AS NEEDED' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:29:36
User opened query 'Please correct spelling of "as" ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:12:03
	(b) (4)	
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'every 12 hours ass needed'	(b) (4), (b) (6)	01 Mar 2021 14:16:38
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23
	(b) (4), (b) (6)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:16:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:14:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 13:19:23

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: ASCORBIC ACID;IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:31:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:31:41
Data point term sent to Coder	System	12 Apr 2021 19:30:52
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 19:29:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: ASCORBIC ACID;IRON PENTACARBONYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:23:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:23:25
User closed query 'Per DM CLR: Please note this medication overlaps with CM #s 15 and 19. Please reconcile if these are duplicate and remove duplicate data if applicable. Otherwise, provide explanation.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:25:43
User signature succeeded.	William Smith (b) (4) (b) (4) (b) (4), (b) (6)	04 Apr 2021 23:54:48
Query 'Per DM CLR: Please note this medication overlaps with CM #s 15 and 19. Please reconcile if these are duplicate and remove duplicate data if applicable. Otherwise, provide explanation.' answered with 'Subject has mild anemia and is taking all 3 medications ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:07:54
Data point term sent to Coder	System	01 Apr 2021 16:14:42
Data point term sent to Coder	System	01 Apr 2021 16:00:29
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 15:59:51

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note this medication overlaps with CM #s 15 and 19. Please reconcile if these are duplicate and remove duplicate data if applicable. Otherwise, provide explanation.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:50:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: ASCORBIC ACID;IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 04:52:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 04:52:59
Data point term sent to Coder	System	01 Mar 2021 14:18:39
User entered 'ascorbic acid carbonyl iron'	(b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:29:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:29:59
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User closed query 'please confirm, source log notes "supplement" and prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:53:10
Query 'please confirm, source log notes "supplement" and prophylaxis.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:30:09
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:29:59
User entered 'supplement' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:29:59
User opened query 'please confirm, source log notes "supplement" and prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:24:12
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 16:13:46
User entered 'pre LEFT REVERSE TOTAL SHOULDER' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 15:59:51
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the Dose to include both components and ensure to update Dose Unit corresponding to the Dose as applicable.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:25:48
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the Dose to include both components and ensure to update Dose Unit corresponding to the Dose as applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:53:19
User entered '125-65' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 15:53:12
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the Dose to include both components and ensure to update Dose Unit corresponding to the Dose as applicable.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:48:22
User entered '125'	(b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:18:29

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:46:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:46:08
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	13 Apr 2021 12:10:12 13 Apr 2021 12:09:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:18:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:18:51
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	01 Apr 2021 16:14:42 01 Apr 2021 16:13:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:45:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:45:10
Data point term sent to Coder User entered 'atorvastatin'	System (b) (4), (b) (6)	01 Mar 2021 14:19:40 01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:11:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:11:18
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:09:20
User entered 'prevention of hyperlipidemia during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:09:20
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:26:14
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:13:55
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'medication was giving to subject after the procedure ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:56:30
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:52:07
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:19:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 11:29:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 11:29:53
Data point term sent to Coder	System	14 Apr 2021 11:13:58
Query 'CDM-Coding: The trade name DULCOLAX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4) (b) (4)	14 Apr 2021 11:13:45
' canceled (Site from System).		
User opened query 'CDM-Coding: The trade name DULCOLAX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:33:41
' (Site from System).		
Data point term sent to Coder	System	13 Apr 2021 12:10:12
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:10:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:51:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:51:13
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Apr 2021 16:14:42
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:14:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:41:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:41:13
Data point term sent to Coder	System	01 Mar 2021 14:20:41
User entered 'dulcolax'	(b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:11:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:11:13
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:10:08
User entered 'prevention of constipation due to pain medication during hospitalization' reason for change:	(b) (4), (b) (6)	13 Apr 2021 12:10:08
Data Entry Error		
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:14:04
Entry Error		
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:20:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:49:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:49:55
Data point term sent to Coder	System	13 Apr 2021 12:11:13
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:11:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:52
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder	System	01 Apr 2021 16:15:45
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:14:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:11:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:11:11
Data point term sent to Coder	System	01 Mar 2021 14:36:56

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'cefazolin'	(b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:11:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:11:09
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:11:09
User entered 'prevention of infection due to surgical intervention during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:11:09
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:14:56
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '500'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2012'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:36:02

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 12:14:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 12:14:04
Data point term sent to Coder	System	13 Apr 2021 12:13:14
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:12:40
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 16:16:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 16:16:28
Data point term sent to Coder	System	01 Apr 2021 16:15:45
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:15:05

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 14:53:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 14:53:50
Data point term sent to Coder	System	01 Mar 2021 14:37:57
User entered 'lactated ringers'	(b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:12:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:12:50
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:12:40
User entered 'electrolyte and fluid replacement due to surgery during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:12:40
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 16:15:05
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '1000'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:37:08

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:08:46
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	13 Apr 2021 12:14:15 13 Apr 2021 12:13:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:02:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:02:46
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	01 Apr 2021 16:15:44 01 Apr 2021 16:15:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:23:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:23:46
Data point term sent to Coder	System	01 Mar 2021 14:39:00

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'loratadine'	(b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:13:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:13:24
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:13:24
User entered 'prevention of seasonal allergies during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:13:24
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 16:15:13
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:38:06

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:15:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:15:49
Data point term sent to Coder	System	13 Apr 2021 12:14:15
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:13:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:17:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:17:45
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder	System	01 Apr 2021 16:16:45
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:15:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:39:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:39:50
Data point term sent to Coder	System	01 Mar 2021 14:43:10
User entered 'morphine'	(b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:13:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:13:54
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:13:54
User entered 'prevention of pain due to surgery during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:13:54
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 16:15:47
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'every 2 hours as needed'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:42:22

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:32:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:32:10
Data point term sent to Coder	System	13 Apr 2021 12:15:16
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:14:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:29:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:29:56
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder	System	01 Apr 2021 16:16:45
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:15:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:06:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:06:39
Data point term sent to Coder	System	01 Mar 2021 14:44:11
User entered 'oxycodone'	(b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:14:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:14:20
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:14:20
User entered 'prevention of pain due to surgery during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:14:20
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:15:54
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'every 4 hours as needed'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:43:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:32:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:32:10
Data point term sent to Coder	System	13 Apr 2021 12:15:16
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:15:03
User closed query 'Per DM CLR: Please note this medication overlaps with CM #17. Please reconcile if these are duplicate and either change dates/add stop dates or remove duplicate data if applicable. Otherwise, provide explanation.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:26:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:29:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:29:57
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder	System	01 Apr 2021 16:16:45
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:16:02
Query 'Per DM CLR: Please note this medication overlaps with CM #17. Please reconcile if these are duplicate and either change dates/add stop dates or remove duplicate data if applicable. Otherwise, provide explanation.' answered with 'inactivated cm #17' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:57:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:06:40

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:06:40
User opened query 'Per DM CLR: Please note this medication overlaps with CM #17. Please reconcile if these are duplicate and either change dates/add stop dates or remove duplicate data if applicable. Otherwise, provide explanation.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:54:48
Data point term sent to Coder	System	01 Mar 2021 14:45:12
User entered 'oxycodone'	(b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:15:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:15:03
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:15:03
User entered 'prevention of pain due to surgery during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:15:03
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 16:16:02
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '5'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'every 4 hours as needed'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '24 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:44:47

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 08:14:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	14 Apr 2021 08:14:51
Data point term sent to Coder	System	13 Apr 2021 12:16:17
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 12:15:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Apr 2021 13:09:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Apr 2021 13:09:55
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder	System	01 Apr 2021 16:16:46
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 16:16:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 13:26:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 13:26:58
Data point term sent to Coder	System	01 Mar 2021 14:49:18
User entered 'vancomycin'	(b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:15:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:15:54
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:15:54
User entered 'prevention of infection due to surgery during hospitalization' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:15:54
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:16:10
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '1000'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:48:39

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:20:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:20:43
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	13 Apr 2021 12:16:17 13 Apr 2021 12:16:12
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:45:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:45:56
User signature succeeded.	William Smith (b) (4) (b) (4)	04 Apr 2021 23:54:48
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	01 Apr 2021 16:16:46 01 Apr 2021 16:16:17
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:26:43

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Mar 2021 13:26:43
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	01 Mar 2021 14:50:18
User entered 'naproxen'	(b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:16:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:16:17
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 12:16:12
User entered 'PREVENTION OF PAIN DUE TO SURGERY DURING HOSPITALIZATION' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:16:12
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'WORSENING OF LEFT SHOULDER ACROMIAL FRACTURE' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 16:16:17
User entered 'left reverse total shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '220'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'every 12 hours as needed'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:49:20

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 12:18:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 12:18:04
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 12:17:18
User entered 'zoloft'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered 'anxiety'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered '25'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered '31 Mar 2021'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:44:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:22:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 12:16:44

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:22:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:11
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:40:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 21:41:27

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:49:52
User entered '22 Oct 2020'	(b) (4), (b) (6)	01 Dec 2020 21:42:13

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:49:54
User entered 'left shoulder, reverse arthroplasty'	(b) (4), (b) (6)	16 Dec 2020 22:04:39
reason for change: Data Entry Error		
User entered 'left total shoulder replacement	(b) (4), (b) (6)	01 Dec 2020 21:42:13
(pre-planned)'		

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 21:36:25
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 20:07:26
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 20:07:26
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:49:56
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	01 Dec 2020 21:42:13

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:49:57
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 21:42:13

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:02
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered '22 Oct 2020'	(b) (4), (b) (6)	01 Mar 2021 14:07:44

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:02
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered 'X-ray of left shoulder'	(b) (4), (b) (6)	01 Mar 2021 14:07:44

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:02
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	01 Mar 2021 14:07:44

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:22:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:02
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:07:44

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:05
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered '22 Oct 2020'	(b) (4), (b) (6)	01 Mar 2021 14:08:12

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:05
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered 'MRI of left rotators cuff'	(b) (4), (b) (6)	01 Mar 2021 14:08:12

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:05
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	01 Mar 2021 14:08:12

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:22:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:05
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:08:12

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered '22 Oct 2020'	(b) (4), (b) (6)	01 Mar 2021 14:08:41

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered 'CT scan'	(b) (4), (b) (6)	01 Mar 2021 14:08:41

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	01 Mar 2021 14:08:41

US3712035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:22:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:08
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:36:25
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:08:41

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4) '	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4)	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
User entered '17/Dec/2020 09:17'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:58

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.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'I'	(b) (4), (b) (6)	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Death

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4)	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
User entered '06/Jan/2021 13:02'	System	06 Jan 2021 13:02:57

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:58

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.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:12:17
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 13:02:57

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Death

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4) '	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
User entered '02/Feb/2021 14:12'	System	02 Feb 2021 14:12:27

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:22:58

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.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:55:44
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 14:12:27

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Death

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4)	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
User entered '03/Feb/2021 09:55'	System	03 Feb 2021 14:55:54

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:22:58

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.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:49:23
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 14:55:54

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Death

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4)	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
User entered '12/Feb/2021 08:50'	System	12 Feb 2021 13:50:03

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:22:58

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.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 13:50:03

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Death

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4)	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
User entered '02/Mar/2021 10:01'	System	02 Mar 2021 15:01:08

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:22:58

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.	William Smith (b) (4)	04 Apr 2021 23:54:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 15:01:08

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered		
'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4) '	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:17
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '05/Mar/2021 08:36'	(b) (4) System	05 Mar 2021 13:36:46

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:22:58

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)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:07:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:17
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 13:36:46

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4) '	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:17
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered '02/Apr/2021 15:04'	(b) (4) System	02 Apr 2021 19:04:20

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:22:58

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)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:07:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:17
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 19:04:20

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:29
User entered 'USA-US068-2020-MRNA-1273-P301000005'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Yes (Y)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'No (N)'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'William'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered 'Smith'	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered empty.	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:45:32

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 13:35:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:12:14
Un-reviewed for Safety.	System	02 Mar 2021 15:01:08
User entered (b) (4)	System	02 Mar 2021 15:01:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:00:47
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:45:32
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:45:32
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 14:17:33
User entered (b) (4) '	System	17 Dec 2020 14:16:55

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	04 Apr 2021 23:54:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:12:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 13:02:46
User entered 'US'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 16:08:01
User entered '8'	System	02 Apr 2021 19:04:20
User entered '7'	System	05 Mar 2021 13:36:46
User entered '6'	System	02 Mar 2021 15:01:08
User entered '5'	System	12 Feb 2021 13:50:03
User entered '4'	System	03 Feb 2021 14:55:54
User entered '3'	System	02 Feb 2021 14:12:27
User entered '2'	System	06 Jan 2021 13:02:57
User entered '1'	System	17 Dec 2020 14:17:43

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:22:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:38:37
User entered '19/Apr/2021 11:07'	(b) (4) System	19 Apr 2021 16:08:01

US3712035

Folder: SAE USA-US068-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:22:58

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.	William Smith (b) (4)	23 Apr 2021 21:38:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:08:01