

US3752010 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:40:55

All time stamps listed in this document are displayed in GMT

US3752010

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 17:59:00

Generated On: 10 Jun 2021 09:40:55

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[Participant ID](#)

US3752010

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

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US3752010

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3752010

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Date of Informed Consent ( <i>dd MMM yyyy</i> )	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3752010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3752010

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	MYOCARDIAL INFARCTION
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 (2)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	2 CORONARY STENTS
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 (3)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	VERTICAL SLEEVE GASTRECTOMY
Start date (dd MMM yyyy)	UN FEB 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 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	NASAL DEVIATION SURGERY RIGHT
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	RENAL STONES
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 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	COMPLETE HYSTERECTOMY (ASSOCIATED CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	MENOPAUSE AFTER HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	GOUT
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	DEPRESSION AFTER HUSBAND'S DEATH
Start date (dd MMM yyyy)	UN UNK 2009
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	RIGHT HAND SQUAMOUS CELL CANCER
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	CHILDBIRTH
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	LEFT TIBULA/FIBULA FRACTURE
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	CORONARY ARTERY ABLATION (UNKNOWN ASSOCIATED CONDITION)
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 (19)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	NASAL DEVIATION RIGHT
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3752010

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3752010

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	ALOPECIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3752010

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	GASTROESOPHAGEAL REFLUX DISEASE (RESOLVED AFTER VERTICAL SLEEVE)
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 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

US3752010

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	LAPAROTOMY FOR RENAL STONES
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

US3752010

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	LAPAROTOMY FOR RENAL STONES
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

US3752010

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	RENAL STONE MANIPULATION
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982



US3752010

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	TOPICAL BENZOYL PEROXIDE ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3752010

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	CARDIAC MURMUR (FINAL DIAGNOSIS UNKNOWN)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3752010

Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 20 Mar 2021 01:28:27

Generated On: 10 Jun 2021 09:40:55

Condition	GASTROESOPHAGEAL REFLUX
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	02 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

US3752010

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:47 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 13:47
Height ( <i>xxx.x</i> )	164 cm
Weight ( <i>xxx.x</i> )	177 lb
BMI ( <i>xxx.x</i> )	29.91320 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 17:59:22

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Date of assessment (dd MMM yyyy) 07 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1996

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 17:59:22

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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 ☐

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**Specify**

CLERICAL PAYROLL

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

**No Risk Identified** False

**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 17:59:22

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:59:22

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 185215

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 ☒

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 13:47
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 16:10
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752010

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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.*

US3752010

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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 AUG 2020

What was the treatment time? (00:00-23:59) 15:26 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 15:26

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

US3752010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 AUG 2020

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

07 AUG 2020 14:50



US3752010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:52	07 AUG 2020 14:52
Nasopharyngeal Swab 2	No		

US3752010

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 AUG 2020 15:46

PC Close Date & Time

07 AUG 2020 18:16

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 07 AUG 2020 19:11

PC Close Date & Time 08 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 18:09

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:22

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**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

98.8 °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

11 AUG 2020 19:13

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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

12 AUG 2020 19:28

---

PC Open Date & Time

12 AUG 2020 12:00

---

PC Close Date & Time

13 AUG 2020 11:59

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US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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**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

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

13 AUG 2020 18:50

---

PC Open Date & Time

13 AUG 2020 12:00

---

PC Close Date & Time

14 AUG 2020 11:59

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US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

07 AUG 2020 15:46

PC Close Date & Time

07 AUG 2020 18:16

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

07 AUG 2020 19:11

PC Close Date & Time

08 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

15

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 AUG 2020 21:34

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**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

10 AUG 2020 19:23

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**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

11 AUG 2020 19:13

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**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

12 AUG 2020 19:28

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**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 AUG 2020 18:50

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 AUG 2020 15:46

PC Close Date & Time

07 AUG 2020 18:16

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 AUG 2020 19:11

PC Close Date & Time

08 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

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EAB) (1725)

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US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Yes ☐

PC Time stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59



US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:11
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**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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US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:24
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 19:29
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59



US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 10:54
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3752010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 13:06:21

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3752010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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)	08 SEP 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 12:53
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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)	08 SEP 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 14:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3752010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3752010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 13:30 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 13:30

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

US3752010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

13:01 (24 HR)

Collection date and time (derived)

08 SEP 2020 13:01

US3752010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:59	08 SEP 2020 12:59
Nasopharyngeal Swab 2	No		

US3752010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

08 SEP 2020 13:50

PC Open Date & Time

08 SEP 2020 13:50

PC Close Date & Time

08 SEP 2020 16:20

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	08 SEP 2020 17:16
PC Open Date & Time	08 SEP 2020 17:15
PC Close Date & Time	09 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:01

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 12:00

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.6 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

11 SEP 2020 12:17

---

PC Open Date & Time

11 SEP 2020 12:00

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PC Close Date & Time

12 SEP 2020 11:59

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US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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**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

98.1 °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

12 SEP 2020 12:01

---

PC Open Date & Time

12 SEP 2020 12:00

---

PC Close Date & Time

13 SEP 2020 11:59

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US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 14:10

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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

08 SEP 2020 13:51

PC Open Date & Time

08 SEP 2020 13:50

PC Close Date & Time

08 SEP 2020 16:20

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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

08 SEP 2020 17:16

PC Open Date & Time

08 SEP 2020 17:15

PC Close Date & Time

09 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**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)**

24

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)**

37

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 SEP 2020 12:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

15

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 SEP 2020 12:01

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

12

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 SEP 2020 12:17

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**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)**

23

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)**

19

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

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 6
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - <b>REDNESS AT INJECTION SITE (in mm)</b>	13
Measure the largest size across any injection site redness with the ruler provided.	
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - <b>SWELLING/HARDNESS AT INJECTION SITE (in mm)</b>	8
Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	13 SEP 2020 14:11
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**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

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 13:52
PC Open Date & Time	08 SEP 2020 13:50
PC Close Date & Time	08 SEP 2020 16:20

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:17
PC Open Date & Time	08 SEP 2020 17:15
PC Close Date & Time	09 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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 ☒

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EAB) (1725)

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:03
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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)

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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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US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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 ☒

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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 ☒

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US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:02
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59



US3752010

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 16 SEP 2020 07:41

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3752010

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:40:55

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 07:42
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3752010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 13:06:21

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 13:06:21

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 13:06:21

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3752010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

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

Visit date (dd MMM yyyy)	13 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3752010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3752010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

13:22 (24 HR)

Collection date and time (derived)

13 OCT 2020 13:22

US3752010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 OCT 2020 08:35:40
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

16 OCT 2020 12:00:41

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 17:59:49

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59



US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:16:31

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 00:13:53

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 08:05:46

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

22 NOV 2020 15:42:44

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

29 NOV 2020 01:46:11

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 10:18:25

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

13 DEC 2020 09:35:27

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

20 DEC 2020 00:15:28

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59



US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

27 DEC 2020 22:42:47

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

03 JAN 2021 01:09:29

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

10 JAN 2021 00:01:58

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 21:09:40
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 JAN 2021 14:26:39
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

31 JAN 2021 09:13:06

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

07 FEB 2021 00:01:47

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 09:10:29
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59



US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

21 FEB 2021 00:01:32

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 15:29:04

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

07 MAR 2021 17:17:16

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 14:26:42

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

21 MAR 2021 00:02:34

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 04:49:58

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 00:02:55

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 09:28:07

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59



US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 11:13:46

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:02:49

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

Date and time of submission

02 MAY 2021 00:02:37

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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°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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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°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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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="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"/>



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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"/>

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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10 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 OCT 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 NOV 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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°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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JAN 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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°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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAR 2022 23:59
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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 621

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

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

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

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

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

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

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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°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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3752010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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**US3752010**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:40:55**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 15:29:19

US3752010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:59:21

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:21

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3752010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3752010

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 17:59:22

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 00:20:47

Generated On: 10 Jun 2021 09:40:55

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

Visit date (dd MMM yyyy)	03 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3752010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 11:15:59

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 12:41
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 00:20:47

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3752010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Mar 2021 00:20:47

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00-23:59)	13:04 (24 HR)
Collection date and time (derived)	03 MAR 2021 13:04

US3752010

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:20:47

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 13:38:36

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3752010

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 13:38:36

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3752010**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3752010**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3752010**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:40:55**

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"/>

**US3752010**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:40:55**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3752010

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 17:59:21

Generated On: 10 Jun 2021 09:40:55

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

Visit date (dd MMM yyyy)	18 JAN 2021
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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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US3752010

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 01:13:22

Generated On: 10 Jun 2021 09:40:55

Date of updated informed consent (*dd MMM yyyy*) 18 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3752010

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 17:59:21

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

13:42 (24 HR)

Collection date and time (derived)

18 JAN 2021 13:42



US3752010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 17:59:21

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	13:40
Collection Date and Time (derived)	18 JAN 2021 13:40

US3752010

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 17:59:00

Generated On: 10 Jun 2021 09:40:55

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 14:12:07

Generated On: 10 Jun 2021 09:40:55

AEID

Adverse event

SWOLLEN TONGUE WITH  
UNUSUAL SENSATIONS

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)

09 SEP 2020

Start time (00:00-23:59)

12:00 (24 HR)

AE start date and time (derived)

09 SEP 2020 12:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 SEP 2020

End time (00:00-23:59)

23:59 (24 HR)

AE End Date and Time (derived)

16 SEP 2020 23:59

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 14:12:07

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 14:12:07

Generated On: 10 Jun 2021 09:40:55

AEID	USA-US113-2021-MRNA-1273-P30 1000004
Adverse event	CHOLECYSTITIS
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)	21 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	23 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 14:12:07

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 14:12:07

Generated On: 10 Jun 2021 09:40:55

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ADMITTED WITH  
CHOLECYSTITIS FOR IV  
ANTIBIOTICS PRIOR TO  
UNDERGOING  
CHOLECYSTECTOMY.  
MONITORED INPATIENT FOR 24  
HOURS FOLLOWING  
PROCEDURE DUE TO CURRENT  
USE OF XARELTO. RECORDS  
REQUESTED. FURTHER  
DETAILS AND MEDICATION  
RECONCILIATION PENDING  
RECEIPT.

---

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

---

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 17:59:01

Generated On: 10 Jun 2021 09:40:55

---

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

Yes ☒

No ☐

---

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

---



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 6.25

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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EAB) (1725)

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US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 MAY 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication ALLEGRA

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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 (2)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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"/>

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication LEXAPRO

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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 (3)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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"/>

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐  
No ☒

Indication GOUT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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"/>

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication BIOTIN

Prophylaxis Yes ☐  
No ☒

Indication ALOPECIA

Dose per administration 10000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 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"/>

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication CALCIUM CITRATE

Prophylaxis Yes ☒  
No ☐

Indication MULTI SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
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US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 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 (9)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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)		09 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 checked="" type="radio"/>
	No	<input 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 (10)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication SEASONAL INFLUENZA  
VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

Dose per administration 0.5

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 (10)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 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 (11)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒  
No ☐

Indication GASTROESOPHAGEAL REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 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 (12)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN POST OP  
CHOLECYSTECTOMY

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication THIAMINE

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY POST OP

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	23 JAN 2021	
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 (14)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication PROTONIX

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY PRE AND  
POST OP

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 (14)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	23 JAN 2021	
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 (15)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication CYOBALAMIN

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY POST OP

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 23 JAN 2021		
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) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication FOLIC ACID

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY POST OP

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 (16)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		23 JAN 2021
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 (17)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication PROBIOTIC LACTOBACILLUS

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY POST OP

Dose per administration 2

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 (17)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
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 (18)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication GABAPENTIN

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY POST OP

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	23 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY PRE AND POST OP

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2451

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

Name of Medication PIPERACILLIN/TAZOBACTAM

Prophylaxis Yes ☒  
No ☐

Indication CHOLECYSTECTOMY PRE OP

Dose per administration 2.25/3.375

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

390 of 2451

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 13 Apr 2021 01:06:18

Generated On: 10 Jun 2021 09:40:55

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 22 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	



US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 17:59:21

Generated On: 10 Jun 2021 09:40:55

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 03:46:21

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 JAN 2021	CHOLECYSTECTOMY	Adverse Event	
20 JAN 2021	ELECTROCARDIOGRAM	Adverse Event	
20 JAN 2021	ABDOMINAL ULTRASOUND	Adverse Event	
22 JAN 2021	ELECTROCARDIOGRAM	Adverse Event	

US3752010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:40:55

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

US3752010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

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 ☐

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 03:46:21

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US113-2021-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 03:46:21

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US113-2021-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/JAN/2021 18:30
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

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 03:46:21

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US113-2021-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/MAR/2021 10:45
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

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 03:46:21

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US113-2021-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:13
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



US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 03:46:21

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US113-2021-MRNA-1273-P301000004
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	27/APR/2021 06:08
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

US3752010 (Prod: Baptist Health Center for Clinical Research)

**US3752010**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:40:55**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:41
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'US3752010'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:09:16

**US3752010**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:09:37

**US3752010**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:09:17

**US3752010**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:09:37

**US3752010**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'SCRN'	System	09 Aug 2020 21:09:37

US3752010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:09:19



**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '67'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'YEARS'	System	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '67'	System	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51



**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:19:51

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Aug 2020'	System	09 Aug 2020 21:10:00



**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2020'	System	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:10:00

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:09:17

**US3752010**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'I'	System	09 Aug 2020 21:10:09



**US3752010**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:10:09

**US3752010**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:40:55**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:20:40

US3752010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Aug 2020 16:22:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:22:23
Data point term sent to Coder	System	10 Aug 2020 16:21:31
User entered 'Myocardial infarction'	(b) (4), (b) (6)	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:21:25



**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2015'	System	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2015'	System	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2015'	System	10 Aug 2020 16:21:25

**US3752010**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2015'	System	10 Aug 2020 16:21:25

US3752010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Oct 2020 07:34:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 07:34:32
Data point term sent to Coder	System	14 Oct 2020 13:43:01
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:42:17
User entered '2 CORONARY STENTS' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:42:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:16:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:16:27
Data point term sent to Coder	System	02 Oct 2020 15:50:18
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1)TWO CORONARY STENTS 2) CORONARY ARTERY ABLATION' (Site from System).	System	02 Oct 2020 15:50:15
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1)TWO CORONARY STENTS 2) CORONARY ARTERY ABLATION' answered with 'updated' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 15:50:15
Coding entries removed.	(b) (4), (b) (6)	02 Oct 2020 15:50:08
User entered 'TWO CORONARY STENTs' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 15:50:08

US3752010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1)TWO CORONARY STENTS 2) CORONARY ARTERY ABLATION' (Site from System).	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:25:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 18:21:07
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. answered with 'condition leading to this procedure is unknown' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:42:42
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:49:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary arterial stent insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 12:46:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 12:46:44
Data point term sent to Coder	System	10 Aug 2020 16:48:26
User entered 'TWO CORONARY STENTS with coronary artery ablation' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 16:48:02
Data point term sent to Coder	System	10 Aug 2020 16:22:33
User entered 'Two coronary stents'	(b) (4), (b) (6)	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:22:27



**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2015'	System	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2015'	System	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2015'	System	10 Aug 2020 16:22:27

**US3752010**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2015'	System	10 Aug 2020 16:22:27

US3752010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	16 Nov 2020 18:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	16 Nov 2020 18:45:45
Data point term sent to Coder	System	16 Nov 2020 18:44:24
Coding entries removed.	(b) (4), (b) (6)	16 Nov 2020 18:43:25
User entered 'VERTICAL SLEEVE GASTRECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 18:43:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	15 Oct 2020 05:42:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	15 Oct 2020 05:42:33
Data point term sent to Coder	System	14 Oct 2020 13:44:02
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:43:27
User entered 'VERTICAL SLEEVE GASTRECTOMY (unknown associated condition)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:43:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 08:29:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	02 Sep 2020 08:29:46
Data point term sent to Coder	System	31 Aug 2020 15:58:51



US3752010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) GERD 2) VERTICAL SLEEVE GASTRECTOMY' (Site from System).	System	31 Aug 2020 15:58:19
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) GERD 2) VERTICAL SLEEVE GASTRECTOMY' answered with 'DATA ENTRY CORRECTED' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:58:19
User entered 'VERTICAL SLEEVE GASTRECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:58:07
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) GERD 2) VERTICAL SLEEVE GASTRECTOMY' (Site from System).	Coder Import (b) (4)	14 Aug 2020 15:43:14
Data point term sent to Coder	System	10 Aug 2020 16:29:53
User entered 'GERD - RESOLVED WITH VERTICAL SLEEVE GASTRECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 16:29:50
Data point term sent to Coder	System	10 Aug 2020 16:28:45
Coding entries removed.	(b) (4), (b) (6)	10 Aug 2020 16:28:15
User entered 'GERD - Resolved with vertical sleeve' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 16:28:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 16:26:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	10 Aug 2020 16:26:15
Data point term sent to Coder	System	10 Aug 2020 16:25:39
User entered 'GERD'	(b) (4), (b) (6)	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un Feb 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:44:02
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un Feb 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Feb 2020'	System	14 Oct 2020 13:44:02
User entered 'Jan 2010'	System	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2020'	System	14 Oct 2020 13:44:02
User entered '2010'	System	10 Aug 2020 16:25:37



**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Feb 2020'	System	10 Aug 2020 16:25:37

**US3752010**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2020'	System	10 Aug 2020 16:25:37

US3752010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 05:38:29
' (Site from DM).		
Query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	12 Oct 2020 18:11:14
' answered with 'unknown why subject is not on any medication for this condition' (Site from DM).		
User opened query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	12 Oct 2020 17:09:52
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:30:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:30:14
Data point term sent to Coder	System	10 Aug 2020 16:29:52
User entered 'Diabetes'	(b) (4), (b) (6)	10 Aug 2020 16:28:55

**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:28:55

**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:28:55

**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:44:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 13:43:11
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 16:28:55

US3752010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un Feb 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:44:45
User closed query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and remove stop date if appropriate. If this is ongoing, note that treatment is expected for this condition. Otherwise, provide explanation.'	(b) (4), (b) (6)	28 Sep 2020 14:45:10
(Site from DM).		
Query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and remove stop date if appropriate. If this is ongoing, note that treatment is expected for this condition. Otherwise, provide explanation.'	(b) (4), (b) (6)	25 Sep 2020 13:43:17
answered with 'updated' (Site from DM).		
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 13:43:11
User opened query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and remove stop date if appropriate. If this is ongoing, note that treatment is expected for this condition. Otherwise, provide explanation.'	(b) (4), (b) (6)	25 Sep 2020 10:48:41
(Site from DM).		
User entered 'un Feb 2020'	(b) (4), (b) (6)	10 Aug 2020 16:28:55

**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:28:55



**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	10 Aug 2020 16:28:55

**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	10 Aug 2020 16:28:55

**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Feb 2020'	System	14 Oct 2020 13:44:45
User entered empty.	System	25 Sep 2020 13:43:11
User entered 'Feb 2020'	System	10 Aug 2020 16:28:55

**US3752010**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2020'	System	14 Oct 2020 13:44:45
User entered empty.	System	25 Sep 2020 13:43:11
User entered '2020'	System	10 Aug 2020 16:28:55

US3752010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Nasal septal operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Nov 2020 16:02:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:02:52
Data point term sent to Coder	System	02 Oct 2020 16:23:30
User entered 'NASAL DEVIATION Surgery right' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:23:06
Data point term sent to Coder	System	10 Aug 2020 16:31:55
User entered 'Nasal deviation right corrected with surgery'	(b) (4), (b) (6)	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1970'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:01



**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1970'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1970'	System	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1970'	System	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1970'	System	10 Aug 2020 16:31:01

**US3752010**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1970'	System	10 Aug 2020 16:31:01

US3752010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Oct 2020 13:46:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Oct 2020 13:46:35
Data point term sent to Coder	System	14 Oct 2020 13:46:06
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:45:15
User entered 'Seasonal allergies' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:45:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Hay fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:32:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:32:23
Data point term sent to Coder	System	10 Aug 2020 16:31:56
User entered 'Hay fever'	(b) (4), (b) (6)	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1960'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:39



**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1960'	System	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1960'	System	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	10 Aug 2020 16:31:39

**US3752010**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	10 Aug 2020 16:31:39



US3752010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Renal stone - version MedDRA\23.0.	(b) (4) Coder Import	14 Oct 2020 13:50:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	14 Oct 2020 13:50:27
Data point term sent to Coder	System	14 Oct 2020 13:49:14
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:48:37
User entered 'Renal stones' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:48:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Kidney infection, LLT: Kidney infection - version MedDRA\23.0.	(b) (4) Coder Import	09 Sep 2020 13:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	09 Sep 2020 13:19:38
Data point term sent to Coder	System	09 Sep 2020 13:18:17
User closed query 'CDM-Coding: For coding purpose, Please split the term to two terms and record separately as; 1)KIDNEY INFECTION 2)KIDNEY STONES 1972, 1973, 1982 3)kidney STONE LAPAROTOMY & MANIPULATION, please update the term accordingly.' (Site from System).	System	09 Sep 2020 13:17:48
Query 'CDM-Coding: For coding purpose, Please split the term to two terms and record separately as; 1)KIDNEY INFECTION 2)KIDNEY STONES 1972, 1973, 1982 3)kidney STONE LAPAROTOMY & MANIPULATION, please update the term accordingly.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 13:17:48
User entered 'KIDNEY INFECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 13:17:41

US3752010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: For coding purpose, Please split the term to two terms and record separately as; 1) KIDNEY INFECTION 2) KIDNEY STONES 1972, 1973, 1982 3) kidney STONE LAPAROTOMY & MANIPULATION, please update the term accordingly.' (Site from System). Data point term sent to Coder	Coder Import (b) (4) (b) (4)	09 Sep 2020 03:00:30
User entered 'KIDNEY INFECTION WITH KIDNEY STONES 1972, 1973, 1982 with stone laparotomy & manipulation' reason for change: Data Entry Error	System (b) (4), (b) (6)	10 Aug 2020 16:45:23 10 Aug 2020 16:45:21
Data point term sent to Coder	System	10 Aug 2020 16:34:00
User entered 'Kidney infection with kidney stones 1972, 1973, 1982'	(b) (4), (b) (6)	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1982'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1972'	System	10 Aug 2020 16:33:04



**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1972'	System	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1982'	System	10 Aug 2020 16:33:04

**US3752010**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1982'	System	10 Aug 2020 16:33:04

US3752010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 23:24:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 23:24:32
Data point term sent to Coder	System	14 Oct 2020 13:49:10
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:49:10
User entered 'COMPLETE HYSTERECTOMY (associated condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:49:10
User closed query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). Query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'associated condition unknown' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:45:20
User opened query ' Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:43:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:41

US3752010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:36:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:36:21
Data point term sent to Coder	System	10 Aug 2020 16:35:03
User entered 'Complete hysterectomy'	(b) (4), (b) (6) (b) (4)	10 Aug 2020 16:34:23

US3752010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Per DM CLR : Please review "If Surgically sterile, date of surgery" field in Childbearing Potential eCRF as date of surgery (UN UNK 1998) does not match with this MH entry timeframe (UN UNK 1996-UN UNK 1996). Please reconcile and update data as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:45:18
Query 'Per DM CLR : Please review "If Surgically sterile, date of surgery" field in Childbearing Potential eCRF as date of surgery (UN UNK 1998) does not match with this MH entry timeframe (UN UNK 1996-UN UNK 1996). Please reconcile and update data as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:44:49
User opened query 'Per DM CLR : Please review "If Surgically sterile, date of surgery" field in Childbearing Potential eCRF as date of surgery (UN UNK 1998) does not match with this MH entry timeframe (UN UNK 1996-UN UNK 1996). Please reconcile and update data as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:47:59
User entered 'un UNK 1996'	(b) (4), (b) (6)	10 Aug 2020 16:34:23

**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:34:23

**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:34:23



**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1996'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:34:23

**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:34:23

**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1996'	System	10 Aug 2020 16:34:23

**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1996'	System	10 Aug 2020 16:34:23

**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1996'	System	10 Aug 2020 16:34:23

**US3752010**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1996'	System	10 Aug 2020 16:34:23

US3752010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Sep 2020 22:30:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:30:50
Data point term sent to Coder	System	10 Aug 2020 16:37:04
User entered 'Menopause after hysterectomy'	(b) (4), (b) (6)	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1997'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:36:29



**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1997'	System	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1997'	System	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1998'	System	10 Aug 2020 16:36:29

**US3752010**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1998'	System	10 Aug 2020 16:36:29



US3752010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import	12 Oct 2020 13:28:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Oct 2020 13:28:14
Data point term sent to Coder	System	12 Oct 2020 13:27:29
User entered 'Coronary artery disease'	(b) (4), (b) (6)	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

**US3752010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

**US3752010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

US3752010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:40:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

**US3752010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

**US3752010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

**US3752010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

**US3752010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16



US3752010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

**US3752010**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	12 Oct 2020 13:26:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Oct 2020 13:26:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	13 Aug 2020 15:39:16

US3752010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update Med History eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 18:21:17
' (Site from DM).		
Query 'Per DM CLR: Please specify the location of GOUT. Review and update Med History eCRF as appropriate.	(b) (4), (b) (6)	25 Sep 2020 13:46:05
' answered with 'location unknown' (Site from DM).		
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update Med History eCRF as appropriate.	(b) (4), (b) (6)	25 Sep 2020 10:48:56
' (Site from DM).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:40:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 16:40:24
Data point term sent to Coder	System	10 Aug 2020 16:39:06
User entered 'Gout'	(b) (4), (b) (6)	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:39:09
User entered 'un UNK 2018'	(b) (4), (b) (6)	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:38:38



**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2018'	System	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2018'	System	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2019'	System	10 Aug 2020 16:39:09
User entered 'Jan 2018'	System	10 Aug 2020 16:38:38

**US3752010**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2019'	System	10 Aug 2020 16:39:09
User entered '2018'	System	10 Aug 2020 16:38:38

US3752010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:28:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 20:28:17
Data point term sent to Coder	System	02 Oct 2020 16:20:25
Coding entries removed.	(b) (4), (b) (6)	02 Oct 2020 16:19:46
User entered 'DEPRESSION AFTER HUSBAND'S DEATH' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:19:46
User coded data point as SOC: Psychiatric disorders, HLGT: Adjustment disorders (incl subtypes), HLT: Adjustment disorders, PT: Adjustment disorder with depressed mood, LLT: Situational depression - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 06:01:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 06:01:12
Data point term sent to Coder	System	10 Aug 2020 16:40:12
User entered 'Depression after husband's death.'	(b) (4), (b) (6)	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:40:01



**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2009'	System	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2009'	System	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2011'	System	10 Aug 2020 16:40:01

**US3752010**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2011'	System	10 Aug 2020 16:40:01

US3752010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	24 Aug 2020 08:03:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 08:03:48
Data point term sent to Coder	System	10 Aug 2020 16:41:13
User entered 'Right hand squamous cell cancer'	(b) (4), (b) (6)	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1996'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:41:10



**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'UN UNK 1996'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1996'	System	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1996'	System	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1996'	System	10 Aug 2020 16:41:10

**US3752010**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1996'	System	10 Aug 2020 16:41:10



US3752010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	14 Oct 2020 13:56:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	14 Oct 2020 13:56:33
Data point term sent to Coder	System	14 Oct 2020 13:55:25
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:54:59
User entered 'CARPAL TUNNEL SURGERY bilaterally' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:54:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Oct 2020 16:23:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	02 Oct 2020 16:23:45
Data point term sent to Coder	System	02 Oct 2020 16:22:29
User entered 'CARPAL TUNNEL Surgery' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:22:01
Data point term sent to Coder	System	02 Oct 2020 16:20:25
Coding entries removed.	(b) (4), (b) (6)	02 Oct 2020 16:20:15
User entered 'CARPAL TUNNEL SYNDROME BILATERALLY RESOLVED WITH SURGERY' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:20:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	10 Aug 2020 18:50:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	10 Aug 2020 18:50:13

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Aug 2020 16:43:17
User entered 'Carpal tunnel syndrome bilaterally resolved with surgery.'	(b) (4), (b) (6)	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'UN UNK 2014' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:22:01
User entered 'UN UNK 1970'	(b) (4), (b) (6)	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2014'	System	02 Oct 2020 16:22:01
User entered 'Jan 1970'	System	10 Aug 2020 16:42:49



**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2014'	System	02 Oct 2020 16:22:01
User entered '1970'	System	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2014'	System	10 Aug 2020 16:42:49

**US3752010**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2014'	System	10 Aug 2020 16:42:49

US3752010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Delivery, LLT: Delivery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Aug 2020 08:18:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 08:18:20
Data point term sent to Coder	System	10 Aug 2020 16:47:25
User entered 'Childbirth'	(b) (4), (b) (6)	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1977'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'UN UNK 1977'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:46:33



**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1977'	System	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1977'	System	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1977'	System	10 Aug 2020 16:46:33

**US3752010**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1977'	System	10 Aug 2020 16:46:33

US3752010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Leg fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 19:06:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:06:32
Data point term sent to Coder	System	10 Aug 2020 16:47:25
User entered 'Left tibula/fibula fracture'	(b) (4), (b) (6)	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Un UNK 1995'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:47:24



**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1995'	System	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1995'	System	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1995'	System	10 Aug 2020 16:47:24

**US3752010**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1995'	System	10 Aug 2020 16:47:24

US3752010

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 05:45:57
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	14 Oct 2020 13:51:19
User entered 'CORONARY ARTERY ABLATION (unknown associated condition)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:51:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\23.0.	(b) (4), (b) (6)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 09:23:20
Data point term sent to Coder	(b) (4)	
User entered 'Coronary artery ablation'	System	02 Oct 2020 15:50:17
	(b) (4), (b) (6)	02 Oct 2020 15:49:46



**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:49:46

**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:49:46

**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:49:46

**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:49:46

**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:49:46

**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2015'	System	02 Oct 2020 15:49:46

**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2015'	System	02 Oct 2020 15:49:46

**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2015'	System	02 Oct 2020 15:49:46



**US3752010**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2015'	System	02 Oct 2020 15:49:46

US3752010

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Oct 2020 16:22:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:22:50
Data point term sent to Coder	System	02 Oct 2020 16:21:28
User entered 'Carpal tunnel syndrome'	(b) (4), (b) (6)	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 16:21:22
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	02 Oct 2020 16:20:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2014' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:21:22
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:20:54



**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2014'	System	02 Oct 2020 16:21:22
User entered empty.	System	02 Oct 2020 16:20:54

**US3752010**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2014'	System	02 Oct 2020 16:21:22
User entered empty.	System	02 Oct 2020 16:20:54

US3752010

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Nasal septum deviation - version MedDRA\\23.0.	(b) (4)	03 Oct 2020 08:25:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 08:25:38
Data point term sent to Coder	(b) (4)	02 Oct 2020 16:24:32
User entered 'Nasal deviation right'	System	02 Oct 2020 16:24:00
	(b) (4), (b) (6)	

**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:24:00

**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:24:00

US3752010

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:40:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 16:24:42
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	02 Oct 2020 16:24:00
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:00

**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1970' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:24:42
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 16:24:00



**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:24:00

**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:24:00

**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:24:00

**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1970'	System	02 Oct 2020 16:24:42
User entered empty.	System	02 Oct 2020 16:24:00

**US3752010**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1970'	System	02 Oct 2020 16:24:42
User entered empty.	System	02 Oct 2020 16:24:00

US3752010

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	(b) (4) Coders Import	02 Oct 2020 16:28:42
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	(b) (4) Coders Import	02 Oct 2020 16:28:42
Data point term sent to Coders System	System	02 Oct 2020 16:27:40
User entered 'Atrial fibrillation'	(b) (4), (b) (6)	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:27:21



**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:27:21

**US3752010**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:27:21

US3752010

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Alopecia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Oct 2020 16:29:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:29:45
Data point term sent to Coder	System	02 Oct 2020 16:28:45
User entered 'Alopecia'	(b) (4), (b) (6)	02 Oct 2020 16:28:44



**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:28:44

**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:28:44

**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:28:44

**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:28:44

**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:28:44

**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:28:44

**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:28:44

**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:28:44



**US3752010**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	02 Oct 2020 16:28:44

US3752010

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 23:44:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:44:49
Data point term sent to Coder	System	14 Oct 2020 13:47:07
User entered 'Gastroesophageal reflux disease (resolved after vertical sleeve)'	(b) (4), (b) (6)	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un Feb 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2010'	System	14 Oct 2020 13:47:00



**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2010'	System	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Feb 2020'	System	14 Oct 2020 13:47:00

**US3752010**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2020'	System	14 Oct 2020 13:47:00

US3752010

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Renal stone removal, LLT: Renal stone removal - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 06:37:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 06:37:10
Data point term sent to Coder	System	14 Oct 2020 13:53:22
User entered 'Laparotomy for renal stones'	(b) (4), (b) (6)	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:59



**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1972'	System	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1972'	System	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1972'	System	14 Oct 2020 13:52:59

**US3752010**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1972'	System	14 Oct 2020 13:52:59

US3752010

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Renal stone removal, LLT: Renal stone removal - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 06:37:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 06:37:10
Data point term sent to Coder	System	14 Oct 2020 13:54:23
User entered 'Laparotomy for renal stones'	(b) (4), (b) (6)	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1973'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:53:37



**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1973'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1973'	System	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1973'	System	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1973'	System	14 Oct 2020 13:53:37

**US3752010**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1973'	System	14 Oct 2020 13:53:37

US3752010

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Renal stone removal, LLT: Renal stone removal - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 12:04:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 12:04:10
Data point term sent to Coder	System	14 Oct 2020 13:54:23
User entered 'Renal stone manipulation'	(b) (4), (b) (6)	14 Oct 2020 13:54:12



**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1982'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:54:12

**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:54:12

**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:54:12

**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'un UNK 1982'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:54:12

**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:54:12

**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1982'	System	14 Oct 2020 13:54:12

**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1982'	System	14 Oct 2020 13:54:12

**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 1982'	System	14 Oct 2020 13:54:12



**US3752010**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '1982'	System	14 Oct 2020 13:54:12

US3752010

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Oct 2020 16:23:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:23:28
Data point term sent to Coder	System	14 Oct 2020 13:57:28
User entered 'Topical benzoyl peroxide allergy'	(b) (4), (b) (6)	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 13:56:54



**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 13:56:54

**US3752010**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 13:56:54

US3752010

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:03:03
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur NOS - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:14:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:14:32
Query 'Per MM, please review and update the term to reflect the final diagnosis ' answered with 'Cardiac murmur heard on physical exam 13OCT2020. Subject stated she was aware of murmur and has follow up with her cardiologist scheduled.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:49:52
Data point term sent to Coder	System	03 Nov 2020 14:49:08
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 14:49:00
User entered 'CARDIAC MURMUR (final diagnosis unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 14:49:00
User opened query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 23:29:22
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:04:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:04:26
Data point term sent to Coder	System	14 Oct 2020 14:03:42
User entered 'Cardiac murmur'	(b) (4), (b) (6)	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:03:16



**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 14:03:16

**US3752010**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered empty.	System	14 Oct 2020 14:03:16

US3752010

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
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 - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 18:21:35
Data point term sent to Coder	(b) (4)	
User entered 'gastroesophageal reflux'	System	19 Mar 2021 18:20:14
	Jamie Pettus (b) (4)	19 Mar 2021 18:20:08
	(b) (4)	

**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'un UNK 2019'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:20:08
	(b) (4)	

**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4)	19 Mar 2021 18:20:08
	Jamie Pettus (b) (4)	
	(b) (4)	



**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:24:08
User entered 'Yes (Y)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:20:08
	(b) (4)	

**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered '02 Feb 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	19 Mar 2021 18:24:08
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	19 Mar 2021 18:20:08
	(b) (4)	

US3752010

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:40:55

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User closed query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	(b) (4)	19 Mar 2021 18:24:14
User entered '0' reason for change: Data Entry Error	Jamie Pettus (b) (4)	19 Mar 2021 18:24:14
User opened query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	(b) (4)	19 Mar 2021 18:24:08
User entered '1' reason for change: Data Entry Error	Jamie Pettus (b) (4)	19 Mar 2021 18:24:08
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:20:08

**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Jan 2019'	System	19 Mar 2021 18:20:08

**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2019'	System	19 Mar 2021 18:20:08

**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'Feb 2020'	System	19 Mar 2021 18:24:08
User entered empty.	System	19 Mar 2021 18:20:08

**US3752010**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '2020'	System	19 Mar 2021 18:24:08
User entered empty.	System	19 Mar 2021 18:20:08

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:49:46



**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:47'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered '07 Aug 2020 13:47'	System	10 Aug 2020 16:49:46

US3752010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Per CDM: Please recheck HEIGHT and WEIGHT and update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:51:15
Query 'Per CDM: Please recheck HEIGHT and WEIGHT and update accordingly' answered with 'Height and weight are as entered in the subject's chart.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 13:34:39
User entered '164' cm reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:31:57
User opened query 'Per CDM: Please recheck HEIGHT and WEIGHT and update accordingly' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:16:41
User entered '164' in	(b) (4), (b) (6)	10 Aug 2020 16:49:46
DataPoint set to visible.	System	09 Aug 2020 21:10:09

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '177' lb	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:49:46
DataPoint set to visible.	System	09 Aug 2020 21:10:09

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
Amendment Manager: User entered '29.91320'	System	16 Sep 2020 23:47:47
User entered '29.9'	System	25 Aug 2020 13:31:57
User entered '4.6'	System	10 Aug 2020 16:49:46
DataPoint set to visible.	System	09 Aug 2020 21:10:09

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'kg/m2'	System	10 Aug 2020 16:49:46
DataPoint set to visible.	System	09 Aug 2020 21:10:09

US3752010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Per CDM: units of measure should not be recorded if value is blank or ND. Please update the unit of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:45:01
Query 'Per CDM: units of measure should not be recorded if value is blank or ND. Please update the unit of measure by selecting ... in the drop down box provided. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 15:59:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 15:59:12
User opened query 'Per CDM: units of measure should not be recorded if value is blank or ND. Please update the unit of measure by selecting ... in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 15:25:25
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 23:34:46
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:14:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 13:14:16
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 07:49:45



US3752010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:15:43
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'DATA ENTRY IN ERROR.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 15:59:47
User entered '098.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:59:38
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:16:18
User entered '98.5' F	(b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:59:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:14:16
User entered '53'	(b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'bpm'	System	10 Aug 2020 16:49:46

US3752010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:14:16
User entered '18'	(b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'breaths/min'	System	10 Aug 2020 16:49:46

US3752010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:14:16
User entered '132'	(b) (4), (b) (6)	10 Aug 2020 16:49:46



**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'mmHg'	System	10 Aug 2020 16:49:46

US3752010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Sep 2020 13:14:16
User entered '72'	(b) (4), (b) (6)	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User entered 'mmHg'	System	10 Aug 2020 16:49:46

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33

**US3752010**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 23:17:33

US3752010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Please ensure physical exam is entered in eCRF. ' (Site from CRA).	(b) (4)	02 Nov 2020 19:32:00
Query 'Please ensure physical exam is entered in eCRF. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:39:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 18:39:17
User opened query 'Please ensure physical exam is entered in eCRF. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:21:32
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	11 Sep 2020 21:00:07
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	11 Sep 2020 20:59:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 20:59:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:36:14
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4)	09 Sep 2020 21:01:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 16:50:07

US3752010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:39:17
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 21:00:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 21:00:07
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 18:36:14
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:36:14
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:01:40
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	09 Sep 2020 21:01:40
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 20:53:54
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 16:50:07

**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:54:28



**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:54:28

**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:54:28

**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:54:28

**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'UN UNK 1996' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:44:26
User entered 'UN UNK 1998'	(b) (4), (b) (6)	10 Aug 2020 16:54:28

**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:54:28

**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:54:28

**US3752010**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:40:55**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:54:28

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05



US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

**Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05



US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Clerical Payroll'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05



US3752010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:17:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:05

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:23

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:23

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:56:23

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'VISIT1'	System	10 Aug 2020 16:56:23



US3752010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:59:07

US3752010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:56:13
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:56:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 19:59:07
User entered '185215' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:59:07

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 19:59:07

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

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)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:57:44

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

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)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:57:44

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:57:44

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:57:44

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:57:44



US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'per CDM: please input ND in height field ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:04:03
Query 'per CDM: please input ND in height field ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:33:34
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	15 Sep 2020 18:33:29
User opened query 'per CDM: please input ND in height field ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:59:44
User closed query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:59:44
Query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'Per query resolution-removed from Day 1' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 12:57:12
User entered empty; reason for change Per Query Resolution	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 12:56:52
User opened query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:35:05
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:15:52
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'DATA ENTRY ERROR. CORRECTED.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 16:03:26

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
User entered '164' cm reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:02:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:36:48
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:56
Query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' canceled (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:39
User opened query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:28
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:04
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:02
User entered '164' cm	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:13:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:36:48
User entered '177' lb	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'per CDM: please input ND in height field ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:04:03
Query 'per CDM: please input ND in height field ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:33:34
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	15 Sep 2020 18:33:29
User opened query 'per CDM: please input ND in height field ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:59:44
User closed query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:59:44
Query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'Per query resolution-removed from Day 1' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 12:57:12
User entered empty; reason for change Per Query Resolution	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 12:56:52
User opened query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:35:05
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:15:52
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'DATA ENTRY ERROR. CORRECTED.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 16:03:26

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
User entered '164' cm reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:02:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:36:48
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:56
Query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' canceled (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:39
User opened query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:28
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:04
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:02
User entered '164' cm	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:13:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:36:48
User entered '177' lb	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54



US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:47'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '07 Aug 2020 13:47'	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 17:00:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:00:45
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:00:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Aug 2020 17:00:45
User entered '53' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:00:45
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'bpm'	System	10 Aug 2020 17:00:45
User entered empty.	System	10 Aug 2020 16:59:54



US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:00:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Aug 2020 17:00:45
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:00:45
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'breaths/min'	System	10 Aug 2020 17:00:45
User entered empty.	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:00:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Aug 2020 17:00:45
User entered '132' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:00:45
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'mmHg'	System	10 Aug 2020 17:00:45
User entered empty.	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:00:45
Query 'Data is required. Please provide.' answered by System	System	10 Aug 2020 17:00:45
data change (Site from System).		10 Aug 2020 17:00:45
User entered '72' reason for change: Data Entry	(b) (4), (b) (6)	10 Aug 2020 17:00:45
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'mmHg'	System	10 Aug 2020 17:00:45
User entered empty.	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'per CDM: please input ND in height field ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:04:03
Query 'per CDM: please input ND in height field ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:33:34
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	15 Sep 2020 18:33:29
User opened query 'per CDM: please input ND in height field ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:59:44
User closed query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:59:44
Query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' answered with 'Per query resolution-removed from Day 1' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 12:57:12
User entered empty; reason for change Per Query Resolution	Haylee Rowe (b) (4) (b) (4)	15 Sep 2020 12:56:52
User opened query 'Per CDM: Response Noted. To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT also should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:35:05
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:15:52
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'DATA ENTRY ERROR. CORRECTED.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 16:03:26

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Height

Audit	User	Time (GMT)
User entered '164' cm reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:02:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:37:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:36:48
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:56
Query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' canceled (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:39
User opened query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:28
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:04
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:15:02
User entered '164' cm	(b) (4), (b) (6)	10 Aug 2020 16:59:54



US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:13:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 13:36:48
User entered '177' lb	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:44:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Post dose vital signs time is correct per protocol.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 17:01:15
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 16:59:54
User entered '16:10'	(b) (4), (b) (6)	10 Aug 2020 16:59:54

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '07 Aug 2020 16:10'	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 17:02:09
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54



**US3752010**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:02:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Aug 2020 17:02:09
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'bpm'	System	10 Aug 2020 17:02:09
User entered empty.	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Respiratory Rate (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:02:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Aug 2020 17:02:09
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'breaths/min'	System	10 Aug 2020 17:02:09
User entered empty.	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:02:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Aug 2020 17:02:09
User entered '137' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'mmHg'	System	10 Aug 2020 17:02:09
User entered empty.	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 17:02:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Aug 2020 17:02:09
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 17:02:09
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 16:59:54
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 16:59:54



US3752010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'mmHg'	System	10 Aug 2020 17:02:09
User entered empty.	System	10 Aug 2020 16:59:54

US3752010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:59:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 21:00:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:36:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	09 Sep 2020 21:02:01
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 20:20:04
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'updated' (Site from DM).	Lauren Evans (b) (4)	01 Sep 2020 15:53:57
User entered 'No (N)' reason for change: Data Entry Error	Lauren Evans (b) (4)	01 Sep 2020 15:53:48

US3752010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 14:17:12
User closed query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 14:17:03
Query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' answered with 'PHYSICAL EXAMINATION WAS PERFORMED ON 07AUG2020.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 16:01:10
User opened query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 21:14:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 17:04:13

US3752010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:59:51
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 21:00:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:36:45
User entered '07 Aug 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	09 Sep 2020 21:02:01
User entered empty; reason for change Data Entry Error	Lauren Evans (b) (4)	01 Sep 2020 15:53:48
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 17:04:13

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:12:07

US3752010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4)	09 Aug 2020 21:12:07
	(b) (4), (b) (6)	

US3752010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:12:07

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'MRNA-1273 OR PLACEBO'	System	09 Aug 2020 21:12:07



US3752010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:12:07

US3752010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '15:26'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:12:07

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '07 Aug 2020 15:26'	System	09 Aug 2020 21:12:07

US3752010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 21:12:07

US3752010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'ONCE'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'INTRAMUSCULAR'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:12

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:12



**US3752010**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '14:50'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:12

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '07 Aug 2020 14:50'	System	13 Aug 2020 15:40:12

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:29

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 15:40:29

US3752010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:29

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '14:52'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:29

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '07 Aug 2020 14:52'	System	13 Aug 2020 15:40:29

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 15:40:29



**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:29

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:40:29

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered empty.	System	13 Aug 2020 15:40:29

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 17:05:15

**US3752010**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'I'	System	10 Aug 2020 17:05:15

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 15:46'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 18:16'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 19:11'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 2'	System	09 Aug 2020 21:12:07



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Aug 2020 11:59'	System	09 Aug 2020 21:12:07



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 3'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:08:29', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '518e9fe0-b0a6-4fa0-9f3c-18cd1cda1772'	System	09 Aug 2020 23:09:48
User entered 'Yes (Y)'	System	09 Aug 2020 23:09:48

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:09:16', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '518e9fe0-b0a6-4fa0-9f3c-18cd1cda1772'	System	09 Aug 2020 23:09:48
User entered '99.6'	System	09 Aug 2020 23:09:48

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:09:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '518e9fe0-b0a6-4fa0-9f3c-18cd1cda1772'	System	09 Aug 2020 23:09:48
User entered 'No (N)'	System	09 Aug 2020 23:09:48

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:09:43', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '518e9fe0-b0a6-4fa0-9f3c-18cd1cda1772'	System	09 Aug 2020 23:09:48
User entered '09 Aug 2020 18:09'	System	09 Aug 2020 23:09:48

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 4'	System	09 Aug 2020 21:12:07



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:21:24', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '87a16a06-8b35-4509-981a-7355833f9ce4'	System	11 Aug 2020 00:22:33
User entered 'Yes (Y)'	System	11 Aug 2020 00:22:33

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:21:35', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '87a16a06-8b35-4509-981a-7355833f9ce4' User entered '99.2'	System	11 Aug 2020 00:22:33
	System	11 Aug 2020 00:22:33

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:21:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '87a16a06-8b35-4509-981a-7355833f9ce4'	System	11 Aug 2020 00:22:33
User entered 'No (N)'	System	11 Aug 2020 00:22:33

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:22:31', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '87a16a06-8b35-4509-981a-7355833f9ce4'	System	11 Aug 2020 00:22:33
User entered '10 Aug 2020 19:22'	System	11 Aug 2020 00:22:33

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 5'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:20', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f617b8bf-ed18-43b2-a763-b4424e6bde95'	System	12 Aug 2020 00:13:39
User entered 'Yes (Y)'	System	12 Aug 2020 00:13:39



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f617b8bf-ed18-43b2-a763-b4424e6bde95' User entered '98.8'	System	12 Aug 2020 00:13:39
	System	12 Aug 2020 00:13:39

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:30', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f617b8bf-ed18-43b2-a763-b4424e6bde95'	System	12 Aug 2020 00:13:39
User entered 'No (N)'	System	12 Aug 2020 00:13:39

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:37', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f617b8bf-ed18-43b2-a763-b4424e6bde95'	System	12 Aug 2020 00:13:39
User entered '11 Aug 2020 19:13'	System	12 Aug 2020 00:13:39

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 6'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:27:56', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '01eb8c08-614d-4150-8f50-14e2152d6d7f' User entered 'Yes (Y)'	System	13 Aug 2020 00:28:13
	System	13 Aug 2020 00:28:13

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:03', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '01eb8c08-614d-4150-8f50-14e2152d6d7f' User entered '98.4'	System	13 Aug 2020 00:28:13
	System	13 Aug 2020 00:28:13



US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:07', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '01eb8c08-614d-4150-8f50-14e2152d6d7f' User entered 'No (N)'	System	13 Aug 2020 00:28:13
	System	13 Aug 2020 00:28:13

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:11', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '01eb8c08-614d-4150-8f50-14e2152d6d7f' User entered '12 Aug 2020 19:28'	System	13 Aug 2020 00:28:13
	System	13 Aug 2020 00:28:13

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 7'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:49:43', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd22d21e7-e5ec-4337-9097-fd2769b48a87'	System	13 Aug 2020 23:50:06
User entered 'Yes (Y)'	System	13 Aug 2020 23:50:06

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:49:49', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd22d21e7-e5ec-4337-9097-fd2769b48a87'	System	13 Aug 2020 23:50:06
User entered '98.2'	System	13 Aug 2020 23:50:06

US3752010

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:49:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd22d21e7-e5ec-4337-9097-fd2769b48a87'	System	13 Aug 2020 23:50:06
User entered 'No (N)'	System	13 Aug 2020 23:50:06



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:50:03', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd22d21e7-e5ec-4337-9097-fd2769b48a87'	System	13 Aug 2020 23:50:06
User entered '13 Aug 2020 18:50'	System	13 Aug 2020 23:50:06

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59



US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 15:46'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 18:16'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59



US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 19:11'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 2'	System	09 Aug 2020 21:12:07



US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Aug 2020 12:00'	System	09 Aug 2020 21:12:07



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 3'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T21:33:45', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4e7146c6-e9a3-459b-87c6-0f786fb361e9'	System	10 Aug 2020 02:34:39
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 02:34:39

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T21:33:50', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4e7146c6-e9a3-459b-87c6-0f786fb361e9' User entered 'No (N)'	System	10 Aug 2020 02:34:39
	System	10 Aug 2020 02:34:39

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T21:33:55', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4e7146c6-e9a3-459b-87c6-0f786fb361e9' User entered 'Yes (Y)'	System	10 Aug 2020 02:34:39
	System	10 Aug 2020 02:34:39

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T21:34:11', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4e7146c6-e9a3-459b-87c6-0f786fb361e9' User entered '15'	System	10 Aug 2020 02:34:39
	System	10 Aug 2020 02:34:39

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T21:34:17', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4e7146c6-e9a3-459b-87c6-0f786fb361e9' User entered 'None (1)'	System	10 Aug 2020 02:34:39
	System	10 Aug 2020 02:34:39

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T21:34:34', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4e7146c6-e9a3-459b-87c6-0f786fb361e9' User entered '09 Aug 2020 21:34'	System	10 Aug 2020 02:34:39
	System	10 Aug 2020 02:34:39



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 4'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:22:45', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f15d6dd5-861a-47a2-a1bc-4e03ab9e2d21' User entered 'None (1)'	System	11 Aug 2020 00:23:19
	System	11 Aug 2020 00:23:19

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:22:49', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f15d6dd5-861a-47a2-a1bc-4e03ab9e2d21' User entered 'No (N)'	System	11 Aug 2020 00:23:19
	System	11 Aug 2020 00:23:19

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:22:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f15d6dd5-861a-47a2-a1bc-4e03ab9e2d21' User entered 'No (N)'	System	11 Aug 2020 00:23:19
	System	11 Aug 2020 00:23:19

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:23:09', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f15d6dd5-861a-47a2-a1bc-4e03ab9e2d21' User entered 'None (1)'	System	11 Aug 2020 00:23:19
	System	11 Aug 2020 00:23:19

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:23:16', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f15d6dd5-861a-47a2-a1bc-4e03ab9e2d21' User entered '10 Aug 2020 19:23'	System	11 Aug 2020 00:23:19
	System	11 Aug 2020 00:23:19



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 5'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:45', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '776b4da9-6162-434e-a1af-892d89c271a0'	System	12 Aug 2020 00:14:02
User entered 'None (1)'	System	12 Aug 2020 00:14:02

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:48', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '776b4da9-6162-434e-a1af-892d89c271a0' User entered 'No (N)'	System	12 Aug 2020 00:14:02
	System	12 Aug 2020 00:14:02

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:52', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '776b4da9-6162-434e-a1af-892d89c271a0' User entered 'No (N)'	System	12 Aug 2020 00:14:02
	System	12 Aug 2020 00:14:02

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:54', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '776b4da9-6162-434e-a1af-892d89c271a0'	System	12 Aug 2020 00:14:02
User entered 'None (1)'	System	12 Aug 2020 00:14:02

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:13:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '776b4da9-6162-434e-a1af-892d89c271a0'	System	12 Aug 2020 00:14:02
User entered '11 Aug 2020 19:13'	System	12 Aug 2020 00:14:02



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 6'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:20', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'c56e0485-617f-4370-89a7-987d5fad55b9'	System	13 Aug 2020 00:28:43
User entered 'None (1)'	System	13 Aug 2020 00:28:43

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:26', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'c56e0485-617f-4370-89a7-987d5fad55b9'	System	13 Aug 2020 00:28:43
User entered 'No (N)'	System	13 Aug 2020 00:28:43

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:29', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'c56e0485-617f-4370-89a7-987d5fad55b9'	System	13 Aug 2020 00:28:43
User entered 'No (N)'	System	13 Aug 2020 00:28:43

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:35', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'c56e0485-617f-4370-89a7-987d5fad55b9'	System	13 Aug 2020 00:28:43
User entered 'None (1)'	System	13 Aug 2020 00:28:43

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'c56e0485-617f-4370-89a7-987d5fad55b9'	System	13 Aug 2020 00:28:43
User entered '12 Aug 2020 19:28'	System	13 Aug 2020 00:28:43



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 7'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:50:08', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9c3c73bd-0c85-41a0-9fed-52d3cbf5c129'	System	13 Aug 2020 23:50:34
User entered 'None (1)'	System	13 Aug 2020 23:50:34

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:50:12', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9c3c73bd-0c85-41a0-9fed-52d3cbf5c129'	System	13 Aug 2020 23:50:34
User entered 'No (N)'	System	13 Aug 2020 23:50:34

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:50:15', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9c3c73bd-0c85-41a0-9fed-52d3cbf5c129'	System	13 Aug 2020 23:50:34
User entered 'No (N)'	System	13 Aug 2020 23:50:34

US3752010

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:50:24', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9c3c73bd-0c85-41a0-9fed-52d3cbf5c129'	System	13 Aug 2020 23:50:34
User entered 'None (1)'	System	13 Aug 2020 23:50:34

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-13T18:50:32', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9c3c73bd-0c85-41a0-9fed-52d3cbf5c129'	System	13 Aug 2020 23:50:34
User entered '13 Aug 2020 18:50'	System	13 Aug 2020 23:50:34



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 15:46'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 18:16'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59



US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '07 Aug 2020 19:11'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Aug 2020 11:59'	System	09 Aug 2020 21:12:07



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 2'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 3'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:10:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0'	System	09 Aug 2020 23:11:47
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:11:47

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:10:35', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0'	System	09 Aug 2020 23:11:47
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:11:47

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:10:47', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0' User entered 'None (0)'	System	09 Aug 2020 23:11:47
	System	09 Aug 2020 23:11:47

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:10:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0' User entered 'None (0)'	System	09 Aug 2020 23:11:47
	System	09 Aug 2020 23:11:47



US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:11:02', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0'	System	09 Aug 2020 23:11:47
User entered 'None (0)'	System	09 Aug 2020 23:11:47

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:11:07', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0' User entered 'None (0)'	System	09 Aug 2020 23:11:47
	System	09 Aug 2020 23:11:47

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:11:13', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0'	System	09 Aug 2020 23:11:47
User entered 'No (N)'	System	09 Aug 2020 23:11:47

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-09T18:11:44', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '190d7fef-ef85-4272-82a3-09ca7c2115d0' User entered '09 Aug 2020 18:11'	System	09 Aug 2020 23:11:47
	System	09 Aug 2020 23:11:47

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 4'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:23:39', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624' User entered 'None (0)'	System	11 Aug 2020 00:24:21
	System	11 Aug 2020 00:24:21



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:23:48', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624' User entered 'None (0)'	System	11 Aug 2020 00:24:21
	System	11 Aug 2020 00:24:21

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:23:53', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624' User entered 'None (0)'	System	11 Aug 2020 00:24:21
	System	11 Aug 2020 00:24:21

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:23:56', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624' User entered 'None (0)'	System	11 Aug 2020 00:24:21
	System	11 Aug 2020 00:24:21

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:23:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624' User entered 'None (0)'	System	11 Aug 2020 00:24:21
	System	11 Aug 2020 00:24:21

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:24:02', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624' User entered 'None (0)'	System	11 Aug 2020 00:24:21
	System	11 Aug 2020 00:24:21

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:24:07', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624'	System	11 Aug 2020 00:24:21
User entered 'No (N)'	System	11 Aug 2020 00:24:21

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-10T19:24:16', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '720f7d74-3718-4f86-a717-9aace855b624'	System	11 Aug 2020 00:24:21
User entered '10 Aug 2020 19:24'	System	11 Aug 2020 00:24:21

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 21:12:07



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 5'	System	09 Aug 2020 21:12:07

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44' User entered 'None (0)'	System	12 Aug 2020 00:14:42
	System	12 Aug 2020 00:14:42

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:20', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44' User entered 'None (0)'	System	12 Aug 2020 00:14:42
	System	12 Aug 2020 00:14:42

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:23', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44' User entered 'None (0)'	System	12 Aug 2020 00:14:42
	System	12 Aug 2020 00:14:42

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44' User entered 'None (0)'	System	12 Aug 2020 00:14:42
	System	12 Aug 2020 00:14:42

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:30', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44' User entered 'None (0)'	System	12 Aug 2020 00:14:42
	System	12 Aug 2020 00:14:42

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:33', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44' User entered 'None (0)'	System	12 Aug 2020 00:14:42
	System	12 Aug 2020 00:14:42



US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:36', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44' User entered 'No (N)'	System	12 Aug 2020 00:14:42
	System	12 Aug 2020 00:14:42

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-11T19:14:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '91bbede3-5766-4aab-a335-67c000216e44'	System	12 Aug 2020 00:14:42
User entered '11 Aug 2020 19:14'	System	12 Aug 2020 00:14:42

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 6'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:48', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb' User entered 'None (0)'	System	13 Aug 2020 00:29:18
	System	13 Aug 2020 00:29:18

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:51', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb' User entered 'None (0)'	System	13 Aug 2020 00:29:18
	System	13 Aug 2020 00:29:18

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:55', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb'	System	13 Aug 2020 00:29:18
User entered 'None (0)'	System	13 Aug 2020 00:29:18



US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:28:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb' User entered 'None (0)'	System	13 Aug 2020 00:29:18
	System	13 Aug 2020 00:29:18

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:29:03', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb' User entered 'None (0)'	System	13 Aug 2020 00:29:18
	System	13 Aug 2020 00:29:18

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:29:07', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb' User entered 'None (0)'	System	13 Aug 2020 00:29:18
	System	13 Aug 2020 00:29:18

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:29:10', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb'	System	13 Aug 2020 00:29:18
User entered 'No (N)'	System	13 Aug 2020 00:29:18

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-12T19:29:14', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '05fd541b-d9f3-49f5-b86c-1982eefc3ffb' User entered '12 Aug 2020 19:29'	System	13 Aug 2020 00:29:18
	System	13 Aug 2020 00:29:18

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 7'	System	09 Aug 2020 21:12:07



US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:53:56', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77' User entered 'None (0)'	System	14 Aug 2020 15:54:19
	System	14 Aug 2020 15:54:19

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:53:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77' User entered 'None (0)'	System	14 Aug 2020 15:54:19
	System	14 Aug 2020 15:54:19

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:54:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77'	System	14 Aug 2020 15:54:19
User entered 'None (0)'	System	14 Aug 2020 15:54:19

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:54:02', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77' User entered 'None (0)'	System	14 Aug 2020 15:54:19
	System	14 Aug 2020 15:54:19

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:54:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77' User entered 'None (0)'	System	14 Aug 2020 15:54:19
	System	14 Aug 2020 15:54:19

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:54:06', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77'	System	14 Aug 2020 15:54:19
User entered 'None (0)'	System	14 Aug 2020 15:54:19

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:54:10', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77'	System	14 Aug 2020 15:54:19
User entered 'No (N)'	System	14 Aug 2020 15:54:19

US3752010

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-08-14T10:54:16', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b313a23-d109-41c9-8645-3aad0d9cfa77'	System	14 Aug 2020 15:54:19
User entered '14 Aug 2020 10:54'	System	14 Aug 2020 15:54:19



**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:33

**US3752010**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:33

**US3752010**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:33

**US3752010**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:33

**US3752010**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Aug 2020 01:50:28

**US3752010**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'I'	System	23 Aug 2020 01:50:28



**US3752010**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Aug 2020 01:50:59

**US3752010**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Aug 2020 01:50:59

**US3752010**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Aug 2020 01:50:59

**US3752010**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Aug 2020 01:50:59

**US3752010**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Aug 2020 01:51:12

**US3752010**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'I'	System	23 Aug 2020 01:51:12

**US3752010**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:36:14

**US3752010**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered '28 Aug 2020'	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:36:14



**US3752010**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:36:14

**US3752010**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:36:14

**US3752010**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:33:58

**US3752010**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'I'	System	08 Sep 2020 18:33:58

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:54

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:54

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:54

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'VISIT2'	System	09 Sep 2020 20:53:54



US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '12:53'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered '08 Sep 2020 12:53'	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:55:37
Query 'Data is required. Please provide.' answered by System	System	09 Sep 2020 20:55:37
data change (Site from System).		09 Sep 2020 20:55:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:55:37
User opened query 'Data is required. Please provide.' (Site from System).		09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19



US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:55:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:55:37
User entered '54' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:55:37
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'bpm'	System	09 Sep 2020 20:55:37
User entered empty.	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:55:37
Query 'Data is required. Please provide.' answered by System	System	09 Sep 2020 20:55:37
data change (Site from System).		09 Sep 2020 20:55:37
User entered '18' reason for change: Data Entry	(b) (4), (b) (6)	09 Sep 2020 20:55:37
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'breaths/min'	System	09 Sep 2020 20:55:37
User entered empty.	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:55:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:55:37
User entered '128' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:55:37
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'mmHg'	System	09 Sep 2020 20:55:37
User entered empty.	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:55:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:55:37
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:55:37
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'mmHg'	System	09 Sep 2020 20:55:37
User entered empty.	System	09 Sep 2020 20:54:19



US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:56:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:56:16
User entered '14:05' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:56:16
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered '08 Sep 2020 14:05'	System	09 Sep 2020 20:56:16
User entered empty.	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:56:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:56:16
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:56:16
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:56:16
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:19



US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:56:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:56:16
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:56:16
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'bpm'	System	09 Sep 2020 20:56:16
User entered empty.	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:56:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:56:16
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:56:16
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'breaths/min'	System	09 Sep 2020 20:56:16
User entered empty.	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:56:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:56:16
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:56:16
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'mmHg'	System	09 Sep 2020 20:56:16
User entered empty.	System	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 20:56:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 20:56:16
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:56:16
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 20:54:19
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:54:19

US3752010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'mmHg'	System	09 Sep 2020 20:56:16
User entered empty.	System	09 Sep 2020 20:54:19



**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:56:34

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:56:34

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:34:53

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:34:53

US3752010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:34:53

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:34:53

US3752010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:34:53

US3752010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:30'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:34:53



**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered '8 Sep 2020 13:30'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:34:53

US3752010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'ONCE'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:34:53

US3752010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:56:55

US3752010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:56:55

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:01'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:56:55

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered '08 Sep 2020 13:01'	System	09 Sep 2020 20:56:55



**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '12:59'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '08 Sep 2020 12:59'	System	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:57:08



**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered empty.	System	09 Sep 2020 20:57:08

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:57:12

**US3752010**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '1'	System	09 Sep 2020 20:57:12

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:50:28', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '517bc7d2-b72e-4954-8df7-cdf19cb88db0' User entered 'Yes (Y)'	System	08 Sep 2020 18:50:55
	System	08 Sep 2020 18:50:55

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:50:42', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '517bc7d2-b72e-4954-8df7-cdf19cb88db0' User entered '98.1'	System	08 Sep 2020 18:50:55
	System	08 Sep 2020 18:50:55

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:50:46', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '517bc7d2-b72e-4954-8df7-cdf19cb88db0'	System	08 Sep 2020 18:50:55
User entered 'No (N)'	System	08 Sep 2020 18:50:55

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:50:52', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '517bc7d2-b72e-4954-8df7-cdf19cb88db0' User entered '08 Sep 2020 13:50'	System	08 Sep 2020 18:50:55
	System	08 Sep 2020 18:50:55



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 13:50'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 16:20'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:15:45', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b8cc1ecd-03bc-4621-a2bf-212c50abd31a' User entered 'Yes (Y)'	System	08 Sep 2020 22:16:06
	System	08 Sep 2020 22:16:06

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:15:54', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b8cc1ecd-03bc-4621-a2bf-212c50abd31a' User entered '98.2'	System	08 Sep 2020 22:16:06
	System	08 Sep 2020 22:16:06

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:15:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b8cc1ecd-03bc-4621-a2bf-212c50abd31a' User entered 'No (N)'	System	08 Sep 2020 22:16:06
	System	08 Sep 2020 22:16:06

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b8cc1ecd-03bc-4621-a2bf-212c50abd31a' User entered '08 Sep 2020 17:16'	System	08 Sep 2020 22:16:06
	System	08 Sep 2020 22:16:06

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 17:15'	System	08 Sep 2020 18:34:53



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 2'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:00:44', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b4c5210e-72a4-44dd-a4ab-7433c087644a' User entered 'Yes (Y)'	System	09 Sep 2020 17:02:00
	System	09 Sep 2020 17:02:00

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:00:52', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b4c5210e-72a4-44dd-a4ab-7433c087644a' User entered '97.5'	System	09 Sep 2020 17:02:00
	System	09 Sep 2020 17:02:00

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:00:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b4c5210e-72a4-44dd-a4ab-7433c087644a' User entered 'No (N)'	System	09 Sep 2020 17:02:00
	System	09 Sep 2020 17:02:00

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:01:05', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b4c5210e-72a4-44dd-a4ab-7433c087644a' User entered '09 Sep 2020 12:01'	System	09 Sep 2020 17:02:00
	System	09 Sep 2020 17:02:00

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:34:53



US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 3'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:00:35', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6b4b4cb7-4649-433f-b188-59b76f5aefd4'	System	10 Sep 2020 17:01:10
User entered 'Yes (Y)'	System	10 Sep 2020 17:01:10

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:00:41', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6b4b4cb7-4649-433f-b188-59b76f5aefd4' User entered '98.1'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:00:44', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6b4b4cb7-4649-433f-b188-59b76f5aefd4'	System	10 Sep 2020 17:01:10
User entered 'No (N)'	System	10 Sep 2020 17:01:10

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:00:51', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6b4b4cb7-4649-433f-b188-59b76f5aefd4' User entered '10 Sep 2020 12:00'	System	10 Sep 2020 17:01:10
	System	10 Sep 2020 17:01:10

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 4'	System	08 Sep 2020 18:34:53



US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:16:45', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '491e6b33-770b-4ddc-8a75-4ace764f8bf0' User entered 'Yes (Y)'	System	11 Sep 2020 17:17:08
	System	11 Sep 2020 17:17:08

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:16:55', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '491e6b33-770b-4ddc-8a75-4ace764f8bf0' User entered '97.6'	System	11 Sep 2020 17:17:08
	System	11 Sep 2020 17:17:08

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:16:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '491e6b33-770b-4ddc-8a75-4ace764f8bf0'	System	11 Sep 2020 17:17:08
User entered 'No (N)'	System	11 Sep 2020 17:17:08

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:17:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '491e6b33-770b-4ddc-8a75-4ace764f8bf0' User entered '11 Sep 2020 12:17'	System	11 Sep 2020 17:17:08
	System	11 Sep 2020 17:17:08

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 5'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:00:41', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '77331261-2e01-4957-93ab-ad92ae24ea7a' User entered 'Yes (Y)'	System	12 Sep 2020 17:01:50
	System	12 Sep 2020 17:01:50



US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:00:50', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '77331261-2e01-4957-93ab-ad92ae24ea7a' User entered '98.1'	System	12 Sep 2020 17:01:50
	System	12 Sep 2020 17:01:50

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:01:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '77331261-2e01-4957-93ab-ad92ae24ea7a'	System	12 Sep 2020 17:01:50
User entered 'No (N)'	System	12 Sep 2020 17:01:50

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:01:12', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '77331261-2e01-4957-93ab-ad92ae24ea7a' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:01:50
	System	12 Sep 2020 17:01:50

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 6'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:10:41', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '943d0820-a15f-494c-8e4d-658d5d27ff38'	System	13 Sep 2020 19:10:59
User entered 'Yes (Y)'	System	13 Sep 2020 19:10:59

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:10:49', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '943d0820-a15f-494c-8e4d-658d5d27ff38' User entered '97.6'	System	13 Sep 2020 19:10:59
	System	13 Sep 2020 19:10:59



US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:10:52', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '943d0820-a15f-494c-8e4d-658d5d27ff38'	System	13 Sep 2020 19:10:59
User entered 'No (N)'	System	13 Sep 2020 19:10:59

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:10:57', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '943d0820-a15f-494c-8e4d-658d5d27ff38'	System	13 Sep 2020 19:10:59
User entered '13 Sep 2020 14:10'	System	13 Sep 2020 19:10:59

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 7'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:00:52', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6bc6a6fd-d078-4966-8b01-803215d4416e' User entered 'Yes (Y)'	System	14 Sep 2020 17:02:13
	System	14 Sep 2020 17:02:13

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:00:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6bc6a6fd-d078-4966-8b01-803215d4416e' User entered '97.6'	System	14 Sep 2020 17:02:13
	System	14 Sep 2020 17:02:13

US3752010

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:01', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6bc6a6fd-d078-4966-8b01-803215d4416e' User entered 'No (N)'	System	14 Sep 2020 17:02:13
	System	14 Sep 2020 17:02:13



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:13', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6bc6a6fd-d078-4966-8b01-803215d4416e' User entered '14 Sep 2020 12:01'	System	14 Sep 2020 17:02:13
	System	14 Sep 2020 17:02:13

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:51:13', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8b2e4318-332a-4a38-9251-74ada987179f' User entered 'None (1)'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:51:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8b2e4318-332a-4a38-9251-74ada987179f' User entered 'No (N)'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:51:35', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8b2e4318-332a-4a38-9251-74ada987179f' User entered 'No (N)'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:51:45', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8b2e4318-332a-4a38-9251-74ada987179f' User entered 'None (1)'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:51:51', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8b2e4318-332a-4a38-9251-74ada987179f' User entered '08 Sep 2020 13:51'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 13:50'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 16:20'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:15', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'cad98cad-fbae-475d-ba85-7806d53ba296'	System	08 Sep 2020 22:16:38
User entered 'None (1)'	System	08 Sep 2020 22:16:38

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:22', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'cad98cad-fbae-475d-ba85-7806d53ba296'	System	08 Sep 2020 22:16:38
User entered 'No (N)'	System	08 Sep 2020 22:16:38

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:24', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'cad98cad-fbae-475d-ba85-7806d53ba296'	System	08 Sep 2020 22:16:38
User entered 'No (N)'	System	08 Sep 2020 22:16:38

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:31', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'cad98cad-fbae-475d-ba85-7806d53ba296'	System	08 Sep 2020 22:16:38
User entered 'None (1)'	System	08 Sep 2020 22:16:38



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:35', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'cad98cad-fbae-475d-ba85-7806d53ba296'	System	08 Sep 2020 22:16:38
User entered '08 Sep 2020 17:16'	System	08 Sep 2020 22:16:38

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 17:15'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 2'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:01:13', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '69db70c6-433c-4fd9-bf4b-8e527c8c7799'	System	09 Sep 2020 17:03:45
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 17:03:45

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:01:22', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '69db70c6-433c-4fd9-bf4b-8e527c8c7799'	System	09 Sep 2020 17:03:45
User entered 'Yes (Y)'	System	09 Sep 2020 17:03:45

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:01:47', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '69db70c6-433c-4fd9-bf4b-8e527c8c7799' User entered '24'	System	09 Sep 2020 17:03:45
	System	09 Sep 2020 17:03:45

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:01:56', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '69db70c6-433c-4fd9-bf4b-8e527c8c7799'	System	09 Sep 2020 17:03:45
User entered 'Yes (Y)'	System	09 Sep 2020 17:03:45



US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:02:13', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '69db70c6-433c-4fd9-bf4b-8e527c8c7799' User entered '37'	System	09 Sep 2020 17:03:45
	System	09 Sep 2020 17:03:45

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:02:22', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '69db70c6-433c-4fd9-bf4b-8e527c8c7799'	System	09 Sep 2020 17:03:45
User entered 'None (1)'	System	09 Sep 2020 17:03:45

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:02:26', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '69db70c6-433c-4fd9-bf4b-8e527c8c7799' User entered '09 Sep 2020 12:02'	System	09 Sep 2020 17:03:45
	System	09 Sep 2020 17:03:45

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 3'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:01', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90f1a5f7-3d40-4cb4-8e33-09bfd4ab499b'	System	10 Sep 2020 17:02:08
User entered 'None (1)'	System	10 Sep 2020 17:02:08

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:06', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90f1a5f7-3d40-4cb4-8e33-09bfd4ab499b' User entered 'No (N)'	System	10 Sep 2020 17:02:08
	System	10 Sep 2020 17:02:08



US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:09', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90f1a5f7-3d40-4cb4-8e33-09bfd4ab499b' User entered 'Yes (Y)'	System	10 Sep 2020 17:02:08
	System	10 Sep 2020 17:02:08

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:30', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90f1a5f7-3d40-4cb4-8e33-09bfd4ab499b' User entered '15'	System	10 Sep 2020 17:02:08
	System	10 Sep 2020 17:02:08

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:36', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90f1a5f7-3d40-4cb4-8e33-09bfd4ab499b'	System	10 Sep 2020 17:02:08
User entered 'None (1)'	System	10 Sep 2020 17:02:08

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:39', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90f1a5f7-3d40-4cb4-8e33-09bfd4ab499b' User entered '10 Sep 2020 12:01'	System	10 Sep 2020 17:02:08
	System	10 Sep 2020 17:02:08

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 4'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:17:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f9f3e718-9d19-44ae-97fb-11aad4712dda'	System	11 Sep 2020 17:17:57
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 17:17:57



US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:17:30', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f9f3e718-9d19-44ae-97fb-11aad4712dda' User entered 'No (N)'	System	11 Sep 2020 17:17:57
	System	11 Sep 2020 17:17:57

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:17:37', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f9f3e718-9d19-44ae-97fb-11aad4712dda' User entered 'Yes (Y)'	System	11 Sep 2020 17:17:57
	System	11 Sep 2020 17:17:57

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:17:42', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f9f3e718-9d19-44ae-97fb-11aad4712dda' User entered '12'	System	11 Sep 2020 17:17:57
	System	11 Sep 2020 17:17:57

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:17:50', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f9f3e718-9d19-44ae-97fb-11aad4712dda' User entered 'None (1)'	System	11 Sep 2020 17:17:57
	System	11 Sep 2020 17:17:57

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:17:54', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f9f3e718-9d19-44ae-97fb-11aad4712dda'	System	11 Sep 2020 17:17:57
User entered '11 Sep 2020 12:17'	System	11 Sep 2020 17:17:57

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 5'	System	08 Sep 2020 18:34:53



US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:01:25', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a53b8d8b-3a99-4282-bf85-fc3c0b34556a'	System	12 Sep 2020 17:03:14
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:03:14

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:01:28', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a53b8d8b-3a99-4282-bf85-fc3c0b34556a' User entered 'Yes (Y)'	System	12 Sep 2020 17:03:14
	System	12 Sep 2020 17:03:14

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:08', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a53b8d8b-3a99-4282-bf85-fc3c0b34556a' User entered '23'	System	12 Sep 2020 17:03:14
	System	12 Sep 2020 17:03:14

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a53b8d8b-3a99-4282-bf85-fc3c0b34556a' User entered 'Yes (Y)'	System	12 Sep 2020 17:03:14
	System	12 Sep 2020 17:03:14

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:17', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a53b8d8b-3a99-4282-bf85-fc3c0b34556a' User entered '19'	System	12 Sep 2020 17:03:14
	System	12 Sep 2020 17:03:14

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:28', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a53b8d8b-3a99-4282-bf85-fc3c0b34556a' User entered 'None (1)'	System	12 Sep 2020 17:03:14
	System	12 Sep 2020 17:03:14

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:33', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a53b8d8b-3a99-4282-bf85-fc3c0b34556a' User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:03:14
	System	12 Sep 2020 17:03:14

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:34:53



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 6'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:11:10', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd39e53cd-d705-41ca-8bc8-0e8c9ae4c0d6'	System	13 Sep 2020 19:12:02
User entered 'None (1)'	System	13 Sep 2020 19:12:02

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:11:17', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd39e53cd-d705-41ca-8bc8-0e8c9ae4c0d6'	System	13 Sep 2020 19:12:02
User entered 'Yes (Y)'	System	13 Sep 2020 19:12:02

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:11:28', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd39e53cd-d705-41ca-8bc8-0e8c9ae4c0d6' User entered '13'	System	13 Sep 2020 19:12:02
	System	13 Sep 2020 19:12:02

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:11:36', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd39e53cd-d705-41ca-8bc8-0e8c9ae4c0d6'	System	13 Sep 2020 19:12:02
User entered 'Yes (Y)'	System	13 Sep 2020 19:12:02

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:11:50', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd39e53cd-d705-41ca-8bc8-0e8c9ae4c0d6' User entered '8'	System	13 Sep 2020 19:12:02
	System	13 Sep 2020 19:12:02

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:11:53', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd39e53cd-d705-41ca-8bc8-0e8c9ae4c0d6'	System	13 Sep 2020 19:12:02
User entered 'None (1)'	System	13 Sep 2020 19:12:02



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:11:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd39e53cd-d705-41ca-8bc8-0e8c9ae4c0d6' User entered '13 Sep 2020 14:11'	System	13 Sep 2020 19:12:02
	System	13 Sep 2020 19:12:02

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 7'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '45ffb449-b1ad-4f6d-95ae-e043ed82f7a1' User entered 'None (1)'	System	14 Sep 2020 17:03:09
	System	14 Sep 2020 17:03:09

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:21', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '45ffb449-b1ad-4f6d-95ae-e043ed82f7a1' User entered 'No (N)'	System	14 Sep 2020 17:03:09
	System	14 Sep 2020 17:03:09

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:29', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '45ffb449-b1ad-4f6d-95ae-e043ed82f7a1' User entered 'No (N)'	System	14 Sep 2020 17:03:09
	System	14 Sep 2020 17:03:09

US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:38', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '45ffb449-b1ad-4f6d-95ae-e043ed82f7a1' User entered 'None (1)'	System	14 Sep 2020 17:03:09
	System	14 Sep 2020 17:03:09



US3752010

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:44', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '45ffb449-b1ad-4f6d-95ae-e043ed82f7a1' User entered '14 Sep 2020 12:01'	System	14 Sep 2020 17:03:09
	System	14 Sep 2020 17:03:09

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:07', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03' User entered 'None (0)'	System	08 Sep 2020 18:52:46
	System	08 Sep 2020 18:52:46

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:10', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03' User entered 'None (0)'	System	08 Sep 2020 18:52:46
	System	08 Sep 2020 18:52:46

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:14', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03' User entered 'None (0)'	System	08 Sep 2020 18:52:46
	System	08 Sep 2020 18:52:46

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:17', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03' User entered 'None (0)'	System	08 Sep 2020 18:52:46
	System	08 Sep 2020 18:52:46



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:22', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03' User entered 'None (0)'	System	08 Sep 2020 18:52:46
	System	08 Sep 2020 18:52:46

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:29', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03' User entered 'None (0)'	System	08 Sep 2020 18:52:46
	System	08 Sep 2020 18:52:46

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:33', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03'	System	08 Sep 2020 18:52:46
User entered 'No (N)'	System	08 Sep 2020 18:52:46

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T13:52:39', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'db8d7038-54c3-4ae5-a0fa-3b4486dafa03'	System	08 Sep 2020 18:52:46
User entered '08 Sep 2020 13:52'	System	08 Sep 2020 18:52:46

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 13:50'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 16:20'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:41', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0' User entered 'None (0)'	System	08 Sep 2020 22:17:08
	System	08 Sep 2020 22:17:08



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:44', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0' User entered 'None (0)'	System	08 Sep 2020 22:17:08
	System	08 Sep 2020 22:17:08

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:47', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0' User entered 'None (0)'	System	08 Sep 2020 22:17:08
	System	08 Sep 2020 22:17:08

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:49', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0' User entered 'None (0)'	System	08 Sep 2020 22:17:08
	System	08 Sep 2020 22:17:08

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:53', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0' User entered 'None (0)'	System	08 Sep 2020 22:17:08
	System	08 Sep 2020 22:17:08

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:55', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0' User entered 'None (0)'	System	08 Sep 2020 22:17:08
	System	08 Sep 2020 22:17:08

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:16:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0' User entered 'No (N)'	System	08 Sep 2020 22:17:08
	System	08 Sep 2020 22:17:08

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-08T17:17:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'faed1e9e-710c-433c-900e-6c711cba33b0'	System	08 Sep 2020 22:17:08
User entered '08 Sep 2020 17:17'	System	08 Sep 2020 22:17:08

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '08 Sep 2020 17:15'	System	08 Sep 2020 18:34:53



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 2'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:01', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9'	System	09 Sep 2020 17:04:43
User entered 'None (0)'	System	09 Sep 2020 17:04:43

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:06', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9' User entered 'None (0)'	System	09 Sep 2020 17:04:43
	System	09 Sep 2020 17:04:43

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:09', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9'	System	09 Sep 2020 17:04:43
User entered 'None (0)'	System	09 Sep 2020 17:04:43

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:12', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9' User entered 'None (0)'	System	09 Sep 2020 17:04:43
	System	09 Sep 2020 17:04:43

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:17', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9' User entered 'None (0)'	System	09 Sep 2020 17:04:43
	System	09 Sep 2020 17:04:43

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:19', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9'	System	09 Sep 2020 17:04:43
User entered 'None (0)'	System	09 Sep 2020 17:04:43



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:23', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9' User entered 'No (N)'	System	09 Sep 2020 17:04:43
	System	09 Sep 2020 17:04:43

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-09T12:03:30', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '115cb4c4-5fcb-444f-93f0-159c16c245d9' User entered '09 Sep 2020 12:03'	System	09 Sep 2020 17:04:43
	System	09 Sep 2020 17:04:43

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 3'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:50', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175'	System	10 Sep 2020 17:02:47
User entered 'None (0)'	System	10 Sep 2020 17:02:47

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:53', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175' User entered 'None (0)'	System	10 Sep 2020 17:02:47
	System	10 Sep 2020 17:02:47

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:56', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175' User entered 'None (0)'	System	10 Sep 2020 17:02:47
	System	10 Sep 2020 17:02:47



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:01:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175' User entered 'None (0)'	System	10 Sep 2020 17:02:47
	System	10 Sep 2020 17:02:47

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:02:03', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175' User entered 'None (0)'	System	10 Sep 2020 17:02:47
	System	10 Sep 2020 17:02:47

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:02:05', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175'	System	10 Sep 2020 17:02:47
User entered 'None (0)'	System	10 Sep 2020 17:02:47

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:02:08', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175'	System	10 Sep 2020 17:02:47
User entered 'No (N)'	System	10 Sep 2020 17:02:47

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-10T12:02:11', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd3c0c292-a7c9-453b-ab31-77fe5d19a175'	System	10 Sep 2020 17:02:47
User entered '10 Sep 2020 12:02'	System	10 Sep 2020 17:02:47

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 4'	System	08 Sep 2020 18:34:53



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:02', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d' User entered 'None (0)'	System	11 Sep 2020 17:18:28
	System	11 Sep 2020 17:18:28

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d' User entered 'None (0)'	System	11 Sep 2020 17:18:28
	System	11 Sep 2020 17:18:28

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:07', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d' User entered 'None (0)'	System	11 Sep 2020 17:18:28
	System	11 Sep 2020 17:18:28

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:10', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d' User entered 'None (0)'	System	11 Sep 2020 17:18:28
	System	11 Sep 2020 17:18:28

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:13', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d' User entered 'None (0)'	System	11 Sep 2020 17:18:28
	System	11 Sep 2020 17:18:28

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:15', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d' User entered 'None (0)'	System	11 Sep 2020 17:18:28
	System	11 Sep 2020 17:18:28

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d'	System	11 Sep 2020 17:18:28
User entered 'No (N)'	System	11 Sep 2020 17:18:28

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-11T12:18:21', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'eefc8c29-a3e9-47aa-ae78-7c27fb4d818d' User entered '11 Sep 2020 12:18'	System	11 Sep 2020 17:18:28
	System	11 Sep 2020 17:18:28



**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 5'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:47', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93'	System	12 Sep 2020 17:03:40
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:40

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:53', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93'	System	12 Sep 2020 17:03:40
User entered 'No interference with activity (1)'	System	12 Sep 2020 17:03:40

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:56', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93' User entered 'None (0)'	System	12 Sep 2020 17:03:40
	System	12 Sep 2020 17:03:40

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:02:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93' User entered 'None (0)'	System	12 Sep 2020 17:03:40
	System	12 Sep 2020 17:03:40

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:03:02', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93' User entered 'None (0)'	System	12 Sep 2020 17:03:40
	System	12 Sep 2020 17:03:40



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:03:05', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93' User entered 'None (0)'	System	12 Sep 2020 17:03:40
	System	12 Sep 2020 17:03:40

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:03:08', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93'	System	12 Sep 2020 17:03:40
User entered 'No (N)'	System	12 Sep 2020 17:03:40

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-12T12:03:10', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'a2810e90-c26a-4f2b-94e8-a9c10f5abd93' User entered '12 Sep 2020 12:03'	System	12 Sep 2020 17:03:40
	System	12 Sep 2020 17:03:40

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 6'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:09', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae'	System	13 Sep 2020 19:12:42
User entered 'No interference with activity (1)'	System	13 Sep 2020 19:12:42

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:14', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae' User entered 'None (0)'	System	13 Sep 2020 19:12:42
	System	13 Sep 2020 19:12:42



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae' User entered 'None (0)'	System	13 Sep 2020 19:12:42
	System	13 Sep 2020 19:12:42

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:20', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae' User entered 'None (0)'	System	13 Sep 2020 19:12:42
	System	13 Sep 2020 19:12:42

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:25', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae' User entered 'None (0)'	System	13 Sep 2020 19:12:42
	System	13 Sep 2020 19:12:42

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:28', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae' User entered 'None (0)'	System	13 Sep 2020 19:12:42
	System	13 Sep 2020 19:12:42

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:32', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae' User entered 'No (N)'	System	13 Sep 2020 19:12:42
	System	13 Sep 2020 19:12:42

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-13T14:12:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '90d2dad1-d8da-4912-ad9c-3236421d5bae' User entered '13 Sep 2020 14:12'	System	13 Sep 2020 19:12:42
	System	13 Sep 2020 19:12:42

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:34:53



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	08 Sep 2020 18:34:53
User entered 'Day 7'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:01:53', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116'	System	14 Sep 2020 17:03:59
User entered 'No interference with activity (1)'	System	14 Sep 2020 17:03:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:02:07', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116' User entered 'None (0)'	System	14 Sep 2020 17:03:59
	System	14 Sep 2020 17:03:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:02:10', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116' User entered 'None (0)'	System	14 Sep 2020 17:03:59
	System	14 Sep 2020 17:03:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:02:12', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116' User entered 'None (0)'	System	14 Sep 2020 17:03:59
	System	14 Sep 2020 17:03:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:02:17', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116' User entered 'None (0)'	System	14 Sep 2020 17:03:59
	System	14 Sep 2020 17:03:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:02:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116' User entered 'None (0)'	System	14 Sep 2020 17:03:59
	System	14 Sep 2020 17:03:59

US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:02:24', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116' User entered 'No (N)'	System	14 Sep 2020 17:03:59
	System	14 Sep 2020 17:03:59



US3752010

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-14T12:02:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'edc5fc0e-228a-4deb-9426-a5861d278116' User entered '14 Sep 2020 12:02'	System	14 Sep 2020 17:03:59
	System	14 Sep 2020 17:03:59

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:34:53

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:34:53

US3752010

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	13 Sep 2020 19:12:42
User entered 'Day 8'	System	13 Sep 2020 19:12:42

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-16T07:41:43', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'e90e94aa-f19d-40b0-a2f4-48cf65c07e57' User entered 'None (0)'	System	16 Sep 2020 12:41:49
	System	16 Sep 2020 12:41:49

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-16T07:41:48', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'e90e94aa-f19d-40b0-a2f4-48cf65c07e57' User entered '16 Sep 2020 07:41'	System	16 Sep 2020 12:41:49
	System	16 Sep 2020 12:41:49

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:12:42

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:12:42



US3752010

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	13 Sep 2020 19:12:02
User entered 'Day 8'	System	13 Sep 2020 19:12:02

US3752010

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-16T07:41:55', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4a637613-f581-47aa-94ea-af7e27f1ea1b' User entered 'No (N)'	System	16 Sep 2020 12:42:05
	System	16 Sep 2020 12:42:05

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-09-16T07:42:01', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '4a637613-f581-47aa-94ea-af7e27f1ea1b' User entered '16 Sep 2020 07:42'	System	16 Sep 2020 12:42:05
	System	16 Sep 2020 12:42:05

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:12:02

**US3752010**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:12:02

**US3752010**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:36:46

**US3752010**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered '15 Sep 2020'	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:36:46

**US3752010**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:36:46



**US3752010**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:36:46

**US3752010**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:00:39

**US3752010**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'I'	System	14 Oct 2020 14:00:39

**US3752010**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:37:07

**US3752010**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered '22 Sep 2020'	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:37:07

**US3752010**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:37:07

**US3752010**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:37:07

**US3752010**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:00:47



**US3752010**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'I'	System	14 Oct 2020 14:00:47

**US3752010**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:37:29

**US3752010**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered '29 Sep 2020'	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:37:29

**US3752010**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lauren Evans (b) (4)	15 Mar 2021 20:37:29

**US3752010**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:06:21
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 20:37:29

**US3752010**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:00:55

**US3752010**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered 'I'	System	14 Oct 2020 14:00:55

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:18



**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:18

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:18

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'VISIT3'	System	14 Oct 2020 14:01:18

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:15'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered '13 Oct 2020 13:15'	System	14 Oct 2020 14:01:54

US3752010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54



**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '62'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'bpm'	System	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '16'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

US3752010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'breaths/min'	System	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '124'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'mmHg'	System	14 Oct 2020 14:01:54



**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '70'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:01:54

US3752010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered 'mmHg'	System	14 Oct 2020 14:01:54

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:02:04

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:02:04

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:02:25

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:02:25



**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:22'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:02:25

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered '13 Oct 2020 13:22'	System	14 Oct 2020 14:02:25

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:02:29

**US3752010**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:59
User entered '1'	System	14 Oct 2020 14:02:29

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 64'	System	09 Aug 2020 21:12:07

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-07T08:35:01', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '403420e7-a320-44ef-9925-858f4329f66f' User entered 'Yes (Y)'	System	07 Oct 2020 13:35:42
	System	07 Oct 2020 13:35:42

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-07T08:35:06', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '403420e7-a320-44ef-9925-858f4329f66f'	System	07 Oct 2020 13:35:42
User entered 'No (N)'	System	07 Oct 2020 13:35:42

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-07T08:35:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '403420e7-a320-44ef-9925-858f4329f66f' User entered 'No (N)'	System	07 Oct 2020 13:35:42
	System	07 Oct 2020 13:35:42



US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-07T08:35:23', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '403420e7-a320-44ef-9925-858f4329f66f' User entered 'No (N)'	System	07 Oct 2020 13:35:42
	System	07 Oct 2020 13:35:42

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-07T08:35:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '403420e7-a320-44ef-9925-858f4329f66f' User entered '07 Oct 2020 08:35:40'	System	07 Oct 2020 13:35:42
	System	07 Oct 2020 13:35:42

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '07 Oct 2020 00:01'	System	09 Aug 2020 21:12:07

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '11 Oct 2020 23:59'	System	09 Aug 2020 21:12:07

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 71'	System	09 Aug 2020 21:12:07

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

[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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-16T12:00:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '537ebf2e-bb8f-4184-afcc-578c16fcdc52'	System	16 Oct 2020 17:00:51
User entered 'No (N)'	System	16 Oct 2020 17:00:51

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-16T12:00:34', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '537ebf2e-bb8f-4184-afcc-578c16fcdc52'	System	16 Oct 2020 17:00:51
User entered 'No (N)'	System	16 Oct 2020 17:00:51

**US3752010**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-16T12:00:41', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '537ebf2e-bb8f-4184-afcc-578c16fcdc52' User entered '16 Oct 2020 12:00:41'	System	16 Oct 2020 17:00:51
	System	16 Oct 2020 17:00:51



**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '14 Oct 2020 00:01'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '18 Oct 2020 23:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 78'	System	09 Aug 2020 21:12:07

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

[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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-24T17:59:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '63193c97-860d-4aa8-8d5f-4f658c37c576' User entered 'No (N)'	System	24 Oct 2020 22:59:51
	System	24 Oct 2020 22:59:51

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-24T17:59:37', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '63193c97-860d-4aa8-8d5f-4f658c37c576'	System	24 Oct 2020 22:59:51
User entered 'No (N)'	System	24 Oct 2020 22:59:51

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-10-24T17:59:49', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '63193c97-860d-4aa8-8d5f-4f658c37c576' User entered '24 Oct 2020 17:59:49'	System	24 Oct 2020 22:59:51
	System	24 Oct 2020 22:59:51

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '21 Oct 2020 00:01'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '25 Oct 2020 23:59'	System	09 Aug 2020 21:12:07



**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 92'	System	09 Aug 2020 21:12:07

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-06T12:16:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '160b9a64-95c1-4475-bae0-96370fd30cf2' User entered 'No (N)'	System	06 Nov 2020 18:16:38
	System	06 Nov 2020 18:16:38

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-06T12:16:21', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '160b9a64-95c1-4475-bae0-96370fd30cf2'	System	06 Nov 2020 18:16:38
User entered 'No (N)'	System	06 Nov 2020 18:16:38

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-06T12:16:31', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '160b9a64-95c1-4475-bae0-96370fd30cf2' User entered '06 Nov 2020 12:16:31'	System	06 Nov 2020 18:16:38
	System	06 Nov 2020 18:16:38

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '04 Nov 2020 00:01'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '08 Nov 2020 23:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 99'	System	09 Aug 2020 21:12:07

US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

[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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-11T00:13:37', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'fc25537d-5b84-467f-aa3e-b16c8ff99607' User entered 'No (N)'	System	11 Nov 2020 06:13:56
	System	11 Nov 2020 06:13:56



US3752010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-11T00:13:42', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'fc25537d-5b84-467f-aa3e-b16c8ff99607'	System	11 Nov 2020 06:13:56
User entered 'No (N)'	System	11 Nov 2020 06:13:56

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-11T00:13:53', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'fc25537d-5b84-467f-aa3e-b16c8ff99607' User entered '11 Nov 2020 00:13:53'	System	11 Nov 2020 06:13:56
	System	11 Nov 2020 06:13:56

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '11 Nov 2020 00:01'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '15 Nov 2020 23:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered 'Day 106'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-18T08:05:29', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd192e7fa-4a51-4b24-ae0c-713d53e4da78'	System	18 Nov 2020 14:05:48
User entered 'No (N)'	System	18 Nov 2020 14:05:48

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-18T08:05:36', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd192e7fa-4a51-4b24-ae0c-713d53e4da78'	System	18 Nov 2020 14:05:48
User entered 'No (N)'	System	18 Nov 2020 14:05:48

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-18T08:05:46', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd192e7fa-4a51-4b24-ae0c-713d53e4da78' User entered '18 Nov 2020 08:05:46'	System	18 Nov 2020 14:05:48
	System	18 Nov 2020 14:05:48



**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '18 Nov 2020 00:01'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:17:59
Data entry locked.	System	09 Aug 2020 21:12:07
User entered '22 Nov 2020 23:59'	System	09 Aug 2020 21:12:07

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-22T15:42:36', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9d4152fa-56ac-4f5a-a50c-6594b5abe582'	System	22 Nov 2020 21:42:47
User entered 'No (N)'	System	22 Nov 2020 21:42:47

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-22T15:42:39', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9d4152fa-56ac-4f5a-a50c-6594b5abe582'	System	22 Nov 2020 21:42:47
User entered 'No (N)'	System	22 Nov 2020 21:42:47

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-22T15:42:44', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9d4152fa-56ac-4f5a-a50c-6594b5abe582' User entered '22 Nov 2020 15:42:44'	System	22 Nov 2020 21:42:47
	System	22 Nov 2020 21:42:47

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-29T01:46:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '319b19d8-0022-4110-8650-243ec870045d' User entered 'No (N)'	System	29 Nov 2020 07:46:13

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-29T01:44:44', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '319b19d8-0022-4110-8650-243ec870045d' User entered 'No (N)'	System	29 Nov 2020 07:46:13

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-11-29T01:46:11', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '319b19d8-0022-4110-8650-243ec870045d' User entered '29 Nov 2020 01:46:11'	System	29 Nov 2020 07:46:13

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-06T10:18:12', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '3a4be6de-64c6-4e24-9a90-a1cdeb5e0b75'	System	06 Dec 2020 16:18:27
User entered 'No (N)'	System	06 Dec 2020 16:18:27



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-06T10:18:19', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '3a4be6de-64c6-4e24-9a90-a1cdeb5e0b75'	System	06 Dec 2020 16:18:27
User entered 'No (N)'	System	06 Dec 2020 16:18:27

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-06T10:18:25', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '3a4be6de-64c6-4e24-9a90-a1cdcb5e0b75' User entered '06 Dec 2020 10:18:25'	System	06 Dec 2020 16:18:27
	System	06 Dec 2020 16:18:27

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-13T09:35:13', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'ce018847-7527-4097-a84d-9da54f5c9054'	System	13 Dec 2020 15:35:29
User entered 'No (N)'	System	13 Dec 2020 15:35:29

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-13T09:35:18', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'ce018847-7527-4097-a84d-9da54f5c9054' User entered 'No (N)'	System	13 Dec 2020 15:35:29

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-13T09:35:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'ce018847-7527-4097-a84d-9da54f5c9054' User entered '13 Dec 2020 09:35:27'	System	13 Dec 2020 15:35:29
	System	13 Dec 2020 15:35:29



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-20T00:15:05', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '55b22f57-4c72-468e-b58b-079c81ab0045' User entered 'No (N)'	System	20 Dec 2020 06:15:34
	System	20 Dec 2020 06:15:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-20T00:15:16', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '55b22f57-4c72-468e-b58b-079c81ab0045'	System	20 Dec 2020 06:15:34
User entered 'No (N)'	System	20 Dec 2020 06:15:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-20T00:15:28', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '55b22f57-4c72-468e-b58b-079c81ab0045' User entered '20 Dec 2020 00:15:28'	System	20 Dec 2020 06:15:34
	System	20 Dec 2020 06:15:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-27T22:42:31', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f698d8ef-8fed-46f0-8908-692ee23ba870' User entered 'No (N)'	System	28 Dec 2020 04:42:50
	System	28 Dec 2020 04:42:50

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-27T22:42:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f698d8ef-8fed-46f0-8908-692ee23ba870'	System	28 Dec 2020 04:42:50
User entered 'No (N)'	System	28 Dec 2020 04:42:50

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2020-12-27T22:42:47', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f698d8ef-8fed-46f0-8908-692ee23ba870' User entered '27 Dec 2020 22:42:47'	System	28 Dec 2020 04:42:50
	System	28 Dec 2020 04:42:50

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-03T01:09:19', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '78ccf821-0efd-4463-a509-f85a8ebc7cdb' User entered 'No (N)'	System	03 Jan 2021 07:09:34
	System	03 Jan 2021 07:09:34



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-03T01:09:25', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '78ccf821-0efd-4463-a509-f85a8ebc7cdb' User entered 'No (N)'	System	03 Jan 2021 07:09:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-03T01:09:29', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '78ccf821-0efd-4463-a509-f85a8ebc7cdb' User entered '03 Jan 2021 01:09:29'	System	03 Jan 2021 07:09:34
	System	03 Jan 2021 07:09:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-10T00:01:42', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '5b6c695c-8d6b-4a22-a2a7-17855b24eb76'	System	10 Jan 2021 06:02:18
User entered 'No (N)'	System	10 Jan 2021 06:02:18

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-10T00:01:48', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '5b6c695c-8d6b-4a22-a2a7-17855b24eb76'	System	10 Jan 2021 06:02:18
User entered 'No (N)'	System	10 Jan 2021 06:02:18

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-10T00:01:58', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '5b6c695c-8d6b-4a22-a2a7-17855b24eb76'	System	10 Jan 2021 06:02:18
User entered '10 Jan 2021 00:01:58'	System	10 Jan 2021 06:02:18



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-17T21:09:31', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8f17e8d6-6750-4f27-9ede-54b7de4c477b'	System	18 Jan 2021 03:09:42
User entered 'No (N)'	System	18 Jan 2021 03:09:42

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-17T21:09:28', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8f17e8d6-6750-4f27-9ede-54b7de4c477b'	System	18 Jan 2021 03:09:42
User entered 'No (N)'	System	18 Jan 2021 03:09:42

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-17T21:09:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '8f17e8d6-6750-4f27-9ede-54b7de4c477b' User entered '17 Jan 2021 21:09:40'	System	18 Jan 2021 03:09:42

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-24T14:25:55', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '16c0d93c-ecf9-4ea3-b1a5-3b9838690f15' User entered 'Yes (Y)'	System	24 Jan 2021 20:26:51
	System	24 Jan 2021 20:26:51

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-24T14:26:01', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '16c0d93c-ecf9-4ea3-b1a5-3b9838690f15'	System	24 Jan 2021 20:26:51
User entered 'No (N)'	System	24 Jan 2021 20:26:51

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-24T14:26:04', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '16c0d93c-ecf9-4ea3-b1a5-3b9838690f15'	System	24 Jan 2021 20:26:51
User entered 'No (N)'	System	24 Jan 2021 20:26:51

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-24T14:26:12', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '16c0d93c-ecf9-4ea3-b1a5-3b9838690f15' User entered 'Yes (Y)'	System	24 Jan 2021 20:26:51
	System	24 Jan 2021 20:26:51

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Please 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-24T14:26:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '16c0d93c-ecf9-4ea3-b1a5-3b9838690f15'	System	24 Jan 2021 20:26:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 20:26:51

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-24T14:26:39', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '16c0d93c-ecf9-4ea3-b1a5-3b9838690f15' User entered '24 Jan 2021 14:26:39'	System	24 Jan 2021 20:26:51
	System	24 Jan 2021 20:26:51

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-31T09:12:55', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '40691eb4-b4bb-4d06-8298-a90f1061196b' User entered 'No (N)'	System	31 Jan 2021 15:13:09
	System	31 Jan 2021 15:13:09

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-31T09:12:59', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '40691eb4-b4bb-4d06-8298-a90f1061196b'	System	31 Jan 2021 15:13:09
User entered 'No (N)'	System	31 Jan 2021 15:13:09

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-01-31T09:13:06', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '40691eb4-b4bb-4d06-8298-a90f1061196b' User entered '31 Jan 2021 09:13:06'	System	31 Jan 2021 15:13:09
	System	31 Jan 2021 15:13:09

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-07T00:01:35', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'bbf98399-894f-4e27-a778-3d14c86073da' User entered 'No (N)'	System	07 Feb 2021 06:02:15
	System	07 Feb 2021 06:02:15

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-07T00:01:40', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'bbf98399-894f-4e27-a778-3d14c86073da' User entered 'No (N)'	System	07 Feb 2021 06:02:15

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-07T00:01:47', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'bbf98399-894f-4e27-a778-3d14c86073da' User entered '07 Feb 2021 00:01:47'	System	07 Feb 2021 06:02:15
	System	07 Feb 2021 06:02:15

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-14T09:10:20', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '7571b231-596d-4504-b7e6-31bc9926165f'	System	14 Feb 2021 15:10:35
User entered 'No (N)'	System	14 Feb 2021 15:10:35

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-14T09:10:25', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '7571b231-596d-4504-b7e6-31bc9926165f' User entered 'No (N)'	System	14 Feb 2021 15:10:35



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-14T09:10:29', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '7571b231-596d-4504-b7e6-31bc9926165f' User entered '14 Feb 2021 09:10:29'	System	14 Feb 2021 15:10:35
	System	14 Feb 2021 15:10:35

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-21T00:01:22', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '0b781ea9-14fb-498a-8717-c31786152c5a' User entered 'No (N)'	System	21 Feb 2021 06:02:09
	System	21 Feb 2021 06:02:09

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-21T00:01:27', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '0b781ea9-14fb-498a-8717-c31786152c5a' User entered 'No (N)'	System	21 Feb 2021 06:02:09
	System	21 Feb 2021 06:02:09

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-21T00:01:32', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '0b781ea9-14fb-498a-8717-c31786152c5a' User entered '21 Feb 2021 00:01:32'	System	21 Feb 2021 06:02:09
	System	21 Feb 2021 06:02:09

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-28T09:28:51-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd2475544-fb97-491e-a91b-33e54a0cf22e'	System	28 Feb 2021 15:29:07
User entered 'No (N)'	System	28 Feb 2021 15:29:07

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-28T09:28:54-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd2475544-fb97-491e-a91b-33e54a0cf22e'	System	28 Feb 2021 15:29:07
User entered 'No (N)'	System	28 Feb 2021 15:29:07

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-28T09:29:04-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'd2475544-fb97-491e-a91b-33e54a0cf22e' User entered '28 Feb 2021 15:29:04'	System	28 Feb 2021 15:29:07
	System	28 Feb 2021 15:29:07

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-07T17:17:07-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b4e7e40-e97f-4c0a-b12a-9b464c644295'	System	07 Mar 2021 23:18:22
User entered 'No (N)'	System	07 Mar 2021 23:18:22

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-07T17:17:11-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b4e7e40-e97f-4c0a-b12a-9b464c644295'	System	07 Mar 2021 23:18:22
User entered 'No (N)'	System	07 Mar 2021 23:18:22

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-07T17:17:16-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '9b4e7e40-e97f-4c0a-b12a-9b464c644295'	System	07 Mar 2021 23:18:22
User entered '07 Mar 2021 17:17:16'	System	07 Mar 2021 23:18:22

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-14T14:26:34-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b203cb95-d381-40c8-977a-d7b18b3255fd'	System	14 Mar 2021 19:26:46
User entered 'No (N)'	System	14 Mar 2021 19:26:46

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-14T14:26:38-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b203cb95-d381-40c8-977a-d7b18b3255fd'	System	14 Mar 2021 19:26:46
User entered 'No (N)'	System	14 Mar 2021 19:26:46



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-14T14:26:42-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'b203cb95-d381-40c8-977a-d7b18b3255fd' User entered '14 Mar 2021 14:26:42'	System	14 Mar 2021 19:26:46
	System	14 Mar 2021 19:26:46

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-21T00:02:24-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'aa013838-1dd3-4f64-bd7c-cd276d976974'	System	21 Mar 2021 05:03:02
User entered 'No (N)'	System	21 Mar 2021 05:03:02

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-21T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'aa013838-1dd3-4f64-bd7c-cd276d976974'	System	21 Mar 2021 05:03:02
User entered 'No (N)'	System	21 Mar 2021 05:03:02

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-21T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'aa013838-1dd3-4f64-bd7c-cd276d976974' User entered '21 Mar 2021 00:02:34'	System	21 Mar 2021 05:03:02
	System	21 Mar 2021 05:03:02

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-28T04:49:46-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '93d8e3d6-30f4-435d-b51c-b689e07fb032'	System	28 Mar 2021 09:50:02
User entered 'No (N)'	System	28 Mar 2021 09:50:02

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-28T04:49:50-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '93d8e3d6-30f4-435d-b51c-b689e07fb032'	System	28 Mar 2021 09:50:02
User entered 'No (N)'	System	28 Mar 2021 09:50:02

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-03-28T04:49:58-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '93d8e3d6-30f4-435d-b51c-b689e07fb032'	System	28 Mar 2021 09:50:02
User entered '28 Mar 2021 04:49:58'	System	28 Mar 2021 09:50:02

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-04T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'dd0783a5-3ded-484f-8b38-18479a3fecb4' User entered 'No (N)'	System	04 Apr 2021 05:03:00
	System	04 Apr 2021 05:03:00

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-04T00:02:51-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'dd0783a5-3ded-484f-8b38-18479a3fecb4'	System	04 Apr 2021 05:03:00
User entered 'No (N)'	System	04 Apr 2021 05:03:00

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-04T00:02:55-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'dd0783a5-3ded-484f-8b38-18479a3fecb4' User entered '04 Apr 2021 00:02:55'	System	04 Apr 2021 05:03:00
	System	04 Apr 2021 05:03:00

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-11T09:27:57-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6f9e5f8f-7ed1-4339-b5e8-b07ceff35ee5'	System	11 Apr 2021 14:28:10
User entered 'No (N)'	System	11 Apr 2021 14:28:10

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-11T09:28:01-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6f9e5f8f-7ed1-4339-b5e8-b07ceff35ee5'	System	11 Apr 2021 14:28:10
User entered 'No (N)'	System	11 Apr 2021 14:28:10



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-11T09:28:07-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '6f9e5f8f-7ed1-4339-b5e8-b07ceff35ee5'	System	11 Apr 2021 14:28:10
User entered '11 Apr 2021 09:28:07'	System	11 Apr 2021 14:28:10

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-19T11:13:38-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f466ba3c-378a-46a6-afa4-2855660fd6a3'	System	19 Apr 2021 16:16:34
User entered 'No (N)'	System	19 Apr 2021 16:16:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-19T11:13:41-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f466ba3c-378a-46a6-afa4-2855660fd6a3'	System	19 Apr 2021 16:16:34
User entered 'No (N)'	System	19 Apr 2021 16:16:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-19T11:13:46-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'f466ba3c-378a-46a6-afa4-2855660fd6a3'	System	19 Apr 2021 16:16:34
User entered '19 Apr 2021 11:13:46'	System	19 Apr 2021 16:16:34

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-25T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'da6f75ba-4721-433a-8e5a-2f5a80a938b4'	System	25 Apr 2021 05:04:50
User entered 'No (N)'	System	25 Apr 2021 05:04:50

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-25T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'da6f75ba-4721-433a-8e5a-2f5a80a938b4'	System	25 Apr 2021 05:04:50
User entered 'No (N)'	System	25 Apr 2021 05:04:50

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-04-25T00:02:49-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: 'da6f75ba-4721-433a-8e5a-2f5a80a938b4'	System	25 Apr 2021 05:04:50
User entered '25 Apr 2021 00:02:49'	System	25 Apr 2021 05:04:50

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-05-02T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '3ece0cdd-32fc-48cf-91ad-eab5c7badd74'	System	02 May 2021 05:02:55
User entered 'No (N)'	System	02 May 2021 05:02:55

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-05-02T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '3ece0cdd-32fc-48cf-91ad-eab5c7badd74'	System	02 May 2021 05:02:55
User entered 'No (N)'	System	02 May 2021 05:02:55

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-05-02T00:02:37-05:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '3ece0cdd-32fc-48cf-91ad-eab5c7badd74'	System	02 May 2021 05:02:55
User entered '02 May 2021 00:02:37'	System	02 May 2021 05:02:55

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:04:37



**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:04:37

**US3752010**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:04:37
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:04:37

US3752010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:40:55

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)	25 Apr 2021 23:35:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-28T09:29:12-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '7cc2e974-cabd-42a0-9f8e-5a27a3c3c0e6'	System	28 Feb 2021 15:29:21
User entered 'No (N)'	System	28 Feb 2021 15:29:21

**US3752010**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:35:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3A61AAA8-2AB5-4C00-92DD-C5C940A859A7)', Time: '2021-02-28T09:29:19-06:00', User OID: 'PatientReportedOutcome (US3752010)', ODM File OID: '7cc2e974-cabd-42a0-9f8e-5a27a3c3c0e6' User entered '28 Feb 2021 15:29:19'	System	28 Feb 2021 15:29:21
	System	28 Feb 2021 15:29:21



**US3752010**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 17:40:49

**US3752010**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 17:40:49

**US3752010**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 17:40:49

**US3752010**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 17:40:49

**US3752010**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 17:40:53

**US3752010**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:46:53
User entered '1'	System	02 Nov 2020 17:40:53

**US3752010**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:41:45

**US3752010**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:41:45



**US3752010**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:41:45

**US3752010**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:41:45

**US3752010**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:41:49

**US3752010**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'I'	System	07 Dec 2020 17:41:49

**US3752010**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4)	10 Jan 2021 21:49:33
	Amanda Horn (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '7 Jan 2021'	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Jan 2021 21:49:33

**US3752010**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	10 Jan 2021 21:49:33

**US3752010**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4)	10 Jan 2021 21:49:33
	Amanda Horn (b) (4)	
	(b) (4)	



**US3752010**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4)	10 Jan 2021 21:49:39
	Amanda Horn (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'I'	System	10 Jan 2021 21:49:39

**US3752010**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:52:15

**US3752010**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:52:15

**US3752010**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:52:15

**US3752010**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:52:15

**US3752010**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:52:02

**US3752010**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'I'	System	09 Feb 2021 17:52:02



**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:41:45

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered '03 Mar 2021'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:41:45

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered 'Clinic (Clinic)'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:41:45

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'VISIT4'	System	03 Mar 2021 20:41:45

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

US3752010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered '12:41'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered '03 Mar 2021 12:41'	System	31 Mar 2021 19:06:07



US3752010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered '56'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'bpm'	System	31 Mar 2021 19:06:07

US3752010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered '14'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'breaths/min'	System	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered '126'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07



**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'mmHg'	System	31 Mar 2021 19:06:07

US3752010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	03 Apr 2021 11:15:59
User entered '76'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'mmHg'	System	31 Mar 2021 19:06:07

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55

US3752010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:42:05

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered '03 Mar 2021'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:42:05

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:42:52



**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered '03 Mar 2021'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:42:52

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered '13:04'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:42:52

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered '03 Mar 2021 13:04'	System	03 Mar 2021 20:42:52

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:20:47
User entered 'Yes (Y)'	(b) (4) Tonya Cato (b) (4)	03 Mar 2021 20:43:28

**US3752010**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:44:55
User entered 'I'	System	03 Mar 2021 20:43:28

**US3752010**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:38
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:36
User entered 'Yes (Y)'	(b) (4) Timothy Campbell (b) (4) (b) (4)	07 Apr 2021 13:57:06

**US3752010**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:38
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:36
User entered '6 Apr 2021'	(b) (4) Timothy Campbell (b) (4)	07 Apr 2021 13:57:06

**US3752010**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:38
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Timothy Campbell (b) (4) (b) (4)	07 Apr 2021 13:57:06



US3752010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:38
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:36
User entered empty.	(b) (4) Timothy Campbell (b) (4) (b) (4)	07 Apr 2021 13:57:06

**US3752010**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:38
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:38:36
User entered 'Yes (Y)'	(b) (4) Timothy Campbell (b) (4) (b) (4)	07 Apr 2021 13:57:17

**US3752010**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:38
User entered 'I'	System	07 Apr 2021 13:57:17

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:14

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '18 Jan 2021'	(b) (4)	18 Jan 2021 19:50:14
	(b) (4), (b) (6)	

US3752010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:14

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 19:50:14

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:31



**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	16 Apr 2021 01:13:22
User entered '0'	(b) (4) Haylee Rowe (b) (4)	14 Apr 2021 19:39:24
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:22:45

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:31

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	16 Apr 2021 01:13:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	14 Apr 2021 19:39:24
Amendment Manager inserted this DataPoint.	Haylee Rowe (b) (4)	06 Mar 2021 03:22:45
	(b) (4)	
	System	

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:31

US3752010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:40:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:31

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 01:28:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 19:50:31

US3752010

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:40:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 01:28:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 19:50:31

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:31



**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User entered empty.	System	18 Jan 2021 19:50:31

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User entered empty.	System	18 Jan 2021 19:50:31

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:52

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '18 Jan 2021'	(b) (4)	18 Jan 2021 19:50:52
	(b) (4), (b) (6)	

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:42'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:50:52

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User entered '18 Jan 2021 13:42'	System	18 Jan 2021 19:50:52

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:51:02

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:51:02



**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered '13:40'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:51:02

**US3752010**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:57
User entered '18 Jan 2021 13:40'	System	18 Jan 2021 19:51:02

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:40:55**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:33:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:03:50
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:28:53

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 06:26:03
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' answered with 'Per PI, this is not associated with any underlying medical condition. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	23 Dec 2020 21:11:43
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:16:38
User coded data point as SOC: Gastrointestinal disorders, HLGT: Tongue conditions, HLT: Tongue signs and symptoms, PT: Swollen tongue, LLT: Swollen tongue - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:24:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:24:38
Data point term sent to Coder	System	14 Oct 2020 14:10:49
User entered 'Swollen tongue with unusual sensations'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, swollen tongue is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:57:39
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, swollen tongue is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:46:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 14:46:20
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, swollen tongue is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	08 Mar 2021 21:32:51
User entered '09 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '12:00' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 18:48:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 19:40:31
Query 'Data is required. Please provide.' answered with 'Start time is unknown.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 14:10:24
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 14:10:13
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User entered '09 Sep 2020 12:00'	System	08 Jan 2021 18:48:50
User entered empty.	System	14 Oct 2020 14:10:13

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 21:06:02
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Stated that it did resolve a week later; was able to confirm via phone call that it resolved in 16 Sep 2020' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 18:48:58
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 18:48:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 17:54:42
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 17:41:27
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 02:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '16 Sep 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 18:48:50
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Jan 2021 17:54:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Jan 2021 17:54:42
User entered empty; reason for change Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 17:54:42
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Jan 2021 17:43:04
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	08 Jan 2021 17:43:04
User entered '09 Sep 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 17:43:04
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	08 Jan 2021 17:41:27
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 18:49:20
User entered '23:59' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 18:49:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 18:48:50
User entered '24:00' (non-conformant).	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 18:48:50
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	08 Jan 2021 17:55:12
User entered empty; reason for change Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 17:55:12
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	08 Jan 2021 17:54:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 17:48:19
User entered '00:00' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 17:48:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 17:43:04
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 17:43:04
User entered 'un:un' (non-conformant).	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 17:43:04
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 17:41:27
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User entered '16 Sep 2020 23:59'	System	08 Jan 2021 18:49:20
User entered '16 Sep 2020 24:00' (non-conformant).	System	08 Jan 2021 18:48:50
User entered empty.	System	08 Jan 2021 17:54:42
User entered '09 Sep 2020 00:00'	System	08 Jan 2021 17:48:19
User entered '09 Sep 2020 UN:UN' (non-conformant).	System	08 Jan 2021 17:43:04
User entered empty.	System	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	08 Mar 2021 21:32:51
User entered 'Related (RELATED)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Related (RELATED)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	08 Mar 2021 21:32:51
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

US3752010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:40:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:12:07
Signature has been broken.	(b) (4)	29 Mar 2021 18:02:32
User signature succeeded.	Jamie Pettus (b) (4)	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	08 Mar 2021 21:32:51
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	08 Jan 2021 18:48:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User entered '0'	System	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44
User entered '0'	System	14 Oct 2020 14:10:13

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:15:44

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:32:33
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:09
User entered	System	28 Jan 2021 18:30:05
'USA-US113-2021-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	28 Jan 2021 18:30:05



US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 21:32:34
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 14:39:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 14:39:04
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 14:38:27
User entered 'CHOLECYSTITIS'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 21:32:35
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 14:38:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 14:38:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4)	27 Jan 2021 14:38:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 14:38:17
User entered empty.	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:37
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:42
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: please clarify event onset date, per medical records states onset was 20 Jan 2021. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 20:48:09
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 21:32:44
User entered '21 Jan 2021'	Amanda Horn	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '23 Jan 2021'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'I'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: please review date of hospital admission; as per medical records, the subject visited the ER on 20 Jan 2021 and was subsequently admitted. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	03 May 2021 20:48:01
DataPoint Verified.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:11:47
User entered '21 Jan 2021'	(b) (4), (b) (6)	08 Mar 2021 21:32:51
	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '23 Jan 2021'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Not Related (NOT RELATED)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Not Applicable (NOT APPLICABLE)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered '0'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[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. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	15 Mar 2021 13:04:01
' (Site from DM).		
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE. Please review and add a Con Medication as appropriate or update action taken.	Lauren Evans (b) (4)	11 Mar 2021 16:32:51
' answered with 'site is still awaiting medical records on this surgery to confirm medications that were given' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	05 Feb 2021 16:12:04
' (Site from DM).		
User entered 'I'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'I'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17
	(b) (4)	

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 21:32:51
User entered empty.	Amanda Horn (b) (4) (b) (4)	27 Jan 2021 14:38:17

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:09:40
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)	27 Apr 2021 13:09:36
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' answered with 'redacted records have now been sent to the email provided' (Site from Safety).	Lauren Evans (b) (4)	26 Apr 2021 14:56:04
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No COVID-19 testing was completed for this patient. Cholecystectomy, labs, EKG, abdominal single Ultrasound was all performed at the hospital.' (Site from Safety).	Haylee Rowe (b) (4)	26 Apr 2021 13:43:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	24 Apr 2021 15:47:17



US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
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)	24 Apr 2021 15:45:55
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. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:58:18
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:56:19
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:56:07
Comment added 'Will you please provide and email address? We cannot get our fax machine to connect.'	Jamie Pettus (b) (4)	19 Mar 2021 19:17:48
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. Please leave query unanswered until information is available.' answered with 'all lab results in fax' (Site from Safety).	Jamie Pettus (b) (4)	19 Mar 2021 19:03:29

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query unanswered until information is available.' answered with 'sent' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 19:03:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query unanswered until information is available.' answered with 'gallbladder removed' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 19:03:10
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. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:26:54
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:26:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:26:47

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:26:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query unanswered until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:26:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:26:34
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. Please leave query open until information is available.' answered with 'we've requested medical records for this subject twice and have not received them yet' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 18:40:09

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' answered with 'we've requested medical records for this subject twice and have not received them yet' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 18:40:01
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' answered with 'we've requested medical records for this subject twice and have not received them yet' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	12 Mar 2021 18:39:53
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:48:50
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)	12 Mar 2021 17:48:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:48:42

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:48:42
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:48:33
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:48:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:11:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' answered with 'still awaiting medical records' (Site from Safety).	(b) (4) Lauren Evans (b) (4)	11 Mar 2021 16:33:28

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' answered with 'still awaiting medical records' (Site from Safety).	Lauren Evans (b) (4)	11 Mar 2021 16:33:17
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 'still awaiting medical records' (Site from Safety).	Lauren Evans (b) (4)	11 Mar 2021 16:33:05
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:32:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:14:03
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:13:58
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:49:30

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:49:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'we are still awaiting medical records' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	05 Feb 2021 14:27:34
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'we are still awaiting medical records' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	05 Feb 2021 14:27:17
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)	04 Feb 2021 19:07:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:06:53

US3752010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:06:47
User entered 'ADMITTED WITH CHOLECYSTITIS FOR IV ANTIBIOTICS PRIOR TO UNDERGOING CHOLECYSTECTOMY. MONITORED INPATIENT FOR 24 HOURS FOLLOWING PROCEDURE DUE TO CURRENT USE OF XARELTO. RECORDS REQUESTED. FURTHER DETAILS AND MEDICATION RECONCILLIATION PENDING RECEIPT.'	Amanda Horn (b) (4)	27 Jan 2021 14:38:17



**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 14:38:17

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 14:38:32

**US3752010**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Jan 2021 14:38:17

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:40:55

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:34:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 15:28:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 15:28:47
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 15:28:16
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:28:16

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:25:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:25:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Oct 2020 16:25:33 02 Oct 2020 16:25:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:25:27
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 Aug 2020 16:25:27
Data point term sent to Coder User entered 'CARVEDILOL'	System (b) (4), (b) (6)	13 Aug 2020 15:30:38 13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:30:28

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User closed query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 10:33:52
User entered 'Atrial fibrillation' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:25:16
Query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Site will confirm with subject & update SOURCE/EDC accordingly' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:41:24
User opened query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:23:29
User entered 'A-FIB'	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '6.25'	(b) (4), (b) (6)	13 Aug 2020 15:30:28



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'twice daily (BID)'	(b) (4)	13 Aug 2020 15:30:28
	(b) (4), (b) (6)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:30:28

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:49:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:30:28
User entered 'UN May 2015'	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:30:28



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:30:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:30:28

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
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: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 13:29:13
	(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 13:29:13
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 13:28:30
Coding entries removed.	(b) (4), (b) (6)	12 Oct 2020 13:27:53
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: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:49:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 16:49:23
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 16:47:46
Coding entries removed.	(b) (4), (b) (6)	06 Oct 2020 16:46:52
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: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 15:33:20
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Aug 2020 15:33:20
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	13 Aug 2020 15:31:39
User entered 'ALLEGRA'	(b) (4), (b) (6)	13 Aug 2020 15:31:38



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:31:38

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User closed query 'Per CDM Re-query: Please update applicable CRFs as appropriate once details have been gathered. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:42:36
Query 'Per CDM Re-query: Please update applicable CRFs as appropriate once details have been gathered. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:28:00
User entered 'Seasonal allergies' reason for change: New Information	(b) (4), (b) (6)	12 Oct 2020 13:27:53
User closed query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:39:20
User opened query 'Per CDM Re-query: Please update applicable CRFs as appropriate once details have been gathered. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:39:11
User entered 'HAY FEVER' reason for change: New Information	(b) (4), (b) (6)	06 Oct 2020 16:46:52
Query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Site will confirm with subject & update SOURCE/EDC accordingly' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:42:37
User opened query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:24:23
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '180'	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 15:31:38



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:31:38

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:49:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:31:38
User entered 'UN UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:31:38

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:31:38



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:31:38

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 15:33:21
	(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 Aug 2020 15:33:21
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 15:32:40
User entered 'LEXAPRO'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'DEPRESSION'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Aug 2020 15:32:21



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:32:21

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:49:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:32:21
User entered 'UN UNK 2018'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:32:21



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:32:21

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:32:21

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:37:26
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Aug 2020 15:37:26
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 15:35:45
User entered 'ALLOPURINOL'	(b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:34:56

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 14:28:49
' canceled (Site from DM). User opened query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.	(b) (4), (b) (6)	01 Oct 2020 14:26:21
' (Site from DM). User entered 'GOUT'	(b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '100'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:34:56

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 22:12:20
User entered 'UN UNK 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	31 Aug 2020 22:12:20
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 15:56:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 15:56:30
User entered 'UNK 2020' (non-conformant).	(b) (4), (b) (6)	31 Aug 2020 15:56:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 15:34:56
User entered 'U UNK 2020' (non-conformant).	(b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:34:56

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:34:56

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 14:12:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 14:12:34
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 14:11:51
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 14:11:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 13:28:15
	(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 13:28:15
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 13:27:29
Coding entries removed.	(b) (4), (b) (6)	12 Oct 2020 13:27:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 16:29:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 16:29:44
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 16:28:42

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EAB) (1725)

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US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	02 Oct 2020 16:27:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:37:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:37:26
Data point term sent to Coder	System	13 Aug 2020 15:35:46
User entered 'XARELTO'	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:35:45



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Atrial fibrillation' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:11:13
User closed query 'Per CDM Re-query: Please update Indication as appropriate once detail is available. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 14:43:05
Query 'Per CDM Re-query: Please update Indication as appropriate once detail is available. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:27:21
User entered 'Coronary artery disease' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 13:27:14
User opened query 'Per CDM Re-query: Please update Indication as appropriate once detail is available. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:37:01
Query 'Per CDM Re-query: Please update applicable CRFs as appropriate once details have been gathered. ' canceled (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:35:57
Query 'Per CDM Re-query: Please update the indication once details are available. Update CRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:35:12
User closed query 'Per CDM CR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g TIA prophylaxis etc). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:35:08
User opened query 'Per CDM Re-query: Please update the indication once details are available. Update CRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 12:35:06
User opened query 'Per CDM Re-query: Please update applicable CRFs as appropriate once details have been gathered. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:40:07
User entered 'Cardiac disease' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:27:54
Query 'Per CDM CR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g TIA prophylaxis etc). Update Con Med eCRF as appropriate.' answered with 'Site will confirm with subject & update SOURCE/EDC accordingly' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:43:32

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM CR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g TIA prophylaxis etc). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:26:57
User entered 'BLOOD THINNER'	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:35:45

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 15:35:45



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:35:45

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:50:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:35:45
User entered 'UN UNK 2015'	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:35:45

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:35:45



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:35:45

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 06:04:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 06:04:34
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 16:29:46
Coding entries removed.	(b) (4), (b) (6)	02 Oct 2020 16:29:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 15:37:26
	(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 Aug 2020 15:37:26
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 15:36:50
User entered 'BIOTIN'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User closed query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 10:40:36
User entered 'Alopecia' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:29:41
Query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Site will confirm with subject & update SOURCE/EDC accordingly' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:44:08
User opened query 'Per CDM CR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 14:27:56
User entered 'HAIR LOSS'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '10000'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'ug (ug)'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:36:27



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:36:27

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:50:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:36:27
User entered 'UN UNK 2020'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:36:27



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:36:27

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:36:27

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 16:06:05
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 16:06:05
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 15:37:53
User entered 'CALCIUM CITRATE'	(b) (4), (b) (6)	13 Aug 2020 15:37:22

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:25:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'MULTI SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '500'	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 15:37:22



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'three times daily (TID)'	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:37:22

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:50:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:37:22
User entered 'UN UNK 2020'	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 15:37:22



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:37:22

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:37:22

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 15:39:27
	(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 Aug 2020 15:39:27
	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 15:38:56
User entered 'MULTIVITAMIN'	(b) (4), (b) (6)	13 Aug 2020 15:38:14

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 16:26:03
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '1'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 17:50:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 15:38:14
User entered 'UN UNK 2020'	(b) (4), (b) (6)	13 Aug 2020 15:38:14



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:38:14

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 14:14:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 14:14:40
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 14:12:57
User entered 'Acetaminophen'	(b) (4), (b) (6)	14 Oct 2020 14:12:49



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Migraine headaches'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '500'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Oct 2020 14:12:49



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '09 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Oct 2020 14:12:49

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 14:12:49



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 14:12:49

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 07:53:54
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'This does meet EC#9. Subject had influenza vaccine before 14 days after IP vaccine.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:41:56
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 18:00:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:16:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:16:32
Data point term sent to Coder	System	14 Oct 2020 14:14:59
User entered 'Seasonal influenza vaccine'	(b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Prophylaxis for influenza'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0.5' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:07:27
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 14:14:09

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:07:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 14:14:09

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:07:27
User entered 'injection'	(b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:14:09



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User entered empty.	System	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User entered empty.	System	14 Oct 2020 14:14:09

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:29
User entered empty.	System	14 Oct 2020 14:14:09

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
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.	(b) (4) Coder Import (b) (4)	19 Mar 2021 18:21:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 18:21:34
Data point term sent to Coder	System	19 Mar 2021 18:20:14
User entered 'omeprazole'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:19:19

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:49:02
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'Omeprazole is a prophylaxis to prevent gastroesophageal reflux for this patient. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:22:46
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:57:52
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:24:37
User entered 'No (N)'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:19:19

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered 'gastroesophageal reflux'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered '20'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered 'mg (mg)'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered 'once daily (QD)'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered 'Oral (ORAL)'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

US3752010

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered empty.	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered 'un UNK 2019'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered '0'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered 'Yes (Y)'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review stop date of this Con med as MH has a stop date indicated. Please check if dates should be reconciled so there is a match. Otherwise, provide clarification for continued use of medication and update indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:49:09
Query 'Per DM CLR: Please review stop date of this Con med as MH has a stop date indicated. Please check if dates should be reconciled so there is a match. Otherwise, provide clarification for continued use of medication and update indication as appropriate.' answered with 'Still ongoing. pt. takes omeprazole prophylactically ' (Site from DM).	Haylee Rowe (b) (4)	05 Apr 2021 17:36:20
User opened query 'Per DM CLR: Please review stop date of this Con med as MH has a stop date indicated. Please check if dates should be reconciled so there is a match. Otherwise, provide clarification for continued use of medication and update indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:58:06
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered empty.	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
	(b) (4)	
User entered 'No (N)'	Jamie Pettus (b) (4)	19 Mar 2021 18:19:19
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 18:19:19

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 18:19:19

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Mar 2021 18:19:19

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 18:31:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 18:31:11
Data point term sent to Coder	System	19 Mar 2021 18:29:27
User entered 'Hydrocodone/acetaminophen'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:28:35

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'pain post op Cholecystectomy'	(b) (4) Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:28:35



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Also note to provide dose in MG only. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:16:13
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Also note to provide dose in MG only. Update as appropriate. ' answered with 'Corrected the dosage' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:27:18
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:26:57
User entered '7.5/325' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:26:57
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Also note to provide dose in MG only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:57:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered '7.5/325/15ml'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:28:35

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'mg (mg)'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'as needed (PRN)'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Oral (ORAL)'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '04 Feb 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:28:35
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:28:35
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User entered empty.	System	19 Mar 2021 18:28:35

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User entered empty.	System	19 Mar 2021 18:28:35

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:32
User entered empty.	System	19 Mar 2021 18:28:35

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:55:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:55:39
Data point term sent to Coder	System	05 Apr 2021 15:44:33
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:44:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:07:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:07:40
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
Data point term sent to Coder	System	19 Mar 2021 18:32:12
User entered 'thiamine'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:32:06



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:18:50
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'THIAMINE WAS GIVEN POST OP AFTER CHOLECYSTECTOMY' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:45:16
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:44:25
User entered 'CHOLECYSTECTOMY POST OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 15:44:25
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:59:53
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered 'post op'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:32:06

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '100'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'mg (mg)'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'once (ONCE)'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:32:06
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:32:06
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:32:06
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User entered empty.	System	19 Mar 2021 18:32:06

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User entered empty.	System	19 Mar 2021 18:32:06



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:35
User entered empty.	System	19 Mar 2021 18:32:06

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
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: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:22:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:22:49
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:39:12 05 Apr 2021 17:38:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:41:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:41:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
Data point term sent to Coder	System	19 Mar 2021 18:34:13
User entered 'protonix'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:33:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:18:15
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:39:46
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:38:36
User entered 'CHOLECYSTECTOMY PRE AND POST OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:38:36
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:59:43
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered 'pre and post op'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:33:28

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '40'	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'mg (mg)'	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'once daily (QD)'	Jamie Pettus	19 Mar 2021 18:33:28



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Jamie Pettus (b) (4)	19 Mar 2021 18:33:28

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '22 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:33:28
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:33:28

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:33:28
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:33:28
	Jamie Pettus (b) (4)	
	(b) (4)	



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User entered '1'	System	19 Mar 2021 18:33:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User entered '1'	System	19 Mar 2021 18:33:28

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:38
User entered '804 (804)'	System	19 Mar 2021 18:33:28

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:26:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:26:43
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:53:23 05 Apr 2021 17:53:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN, PRODUCTSYNONYM: COBALAMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:10:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:10:33
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
Data point term sent to Coder	System	19 Mar 2021 18:35:14
User entered 'cyobalamin'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:34:41

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:14:49
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'CORRECTED' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:53:34
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:53:18
User entered 'CHOLECYSTECTOMY POST OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:53:18
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:56:13
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered 'post op'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:34:41

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '2000'	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'ug (ug)'	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'once daily (QD)'	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:34:41
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '22 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:34:41
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:34:41
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:34:41
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User entered '1'	System	19 Mar 2021 18:34:41

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User entered '1'	System	19 Mar 2021 18:34:41

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:40
User entered '804 (804)'	System	19 Mar 2021 18:34:41

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:00:27
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 10:00:27
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:54:24 05 Apr 2021 17:54:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 06:50:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 06:50:48
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
Data point term sent to Coder	System	19 Mar 2021 18:36:16
User entered 'folic acid'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:35:36

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	Jamie Pettus	19 Mar 2021 18:35:36

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:15:13
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'CORRECTED' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:54:26
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:54:09
User entered 'CHOLECYSTECTOMY POST OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:54:09
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:56:23
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'post op'	(b) (4) Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:35:36



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'I'	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'mg (mg)'	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'once (ONCE)'	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:35:36
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:35:36
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	Jamie Pettus	19 Mar 2021 18:35:36

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:35:36
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:35:36
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User entered empty.	System	19 Mar 2021 18:35:36

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User entered empty.	System	19 Mar 2021 18:35:36

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:44
User entered empty.	System	19 Mar 2021 18:35:36

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS ACIDOPHILUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:20:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:20:50
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:55:26 05 Apr 2021 17:55:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS ACIDOPHILUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:36:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:36:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
Data point term sent to Coder	System	19 Mar 2021 18:38:20
User entered 'probiotic lactobacillus'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:38:14



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	Jamie Pettus	19 Mar 2021 18:38:14

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:17:50
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:55:34
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:55:19
User entered 'CHOLECYSTECTOMY POST OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 17:55:19
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:59:32
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'with antibiotic'	(b) (4) Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '2'	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'capsule (CAPSULE)'	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'four times daily (QID)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:38:14
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Oral (ORAL)'	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:38:14
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:38:14
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Mar 2021 18:38:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Mar 2021 18:38:20
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	19 Mar 2021 18:38:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Mar 2021 18:38:14
User entered empty.	System	19 Mar 2021 18:38:14
	Jamie Pettus (b) (4)	19 Mar 2021 18:38:14
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User entered '4'	System	19 Mar 2021 18:38:14

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User entered '1'	System	19 Mar 2021 18:38:14



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:47
User entered '804 (804)'	System	19 Mar 2021 18:38:14

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:45
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:32:25 05 Apr 2021 18:31:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 15:26:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 15:26:46
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
Data point term sent to Coder	System	19 Mar 2021 18:40:21
User entered 'gabapentin'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:39:39

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:15:52
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:32:00
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:31:43
User entered 'CHOLECYSTECTOMY POST OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:31:43
Un-reviewed for Data Management.	(b) (4), (b) (6)	04 Apr 2021 06:57:06
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:57:04
Reviewed for Data Management.	(b) (4), (b) (6)	04 Apr 2021 06:56:35
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered 'post op'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:39:39

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '300'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'mg (mg)'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'three times daily (TID)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:39:39
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Oral (ORAL)'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '22 Jan 2021'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:39:39
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:39:39
	Jamie Pettus (b) (4)	
	(b) (4)	



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User entered '3'	System	19 Mar 2021 18:39:39

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User entered '1'	System	19 Mar 2021 18:39:39

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:51
User entered '804 (804)'	System	19 Mar 2021 18:39:39

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 18:34:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	05 Apr 2021 18:34:36
Data point term sent to Coder Coding entries removed.	System	05 Apr 2021 18:33:26
	Haylee Rowe (b) (4)	05 Apr 2021 18:32:31
User signature succeeded.	(b) (4)	
	Priyantha Wijewardane	20 Mar 2021 01:28:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	19 Mar 2021 18:42:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	19 Mar 2021 18:41:22
User entered 'acetaminophen'	Jamie Pettus (b) (4)	19 Mar 2021 18:40:52
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	Jamie Pettus	19 Mar 2021 18:40:52

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:14:22
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:33:21
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:32:31
User entered 'CHOLECYSTECTOMY PRE AND POST OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:32:31
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:55:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User entered 'pre and post op'	Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:40:52

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '650'	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'mg (mg)'	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'four times daily (QID)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:40:52
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Oral (ORAL)'	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '22 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:40:52
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4) Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:40:52

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '23 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:40:52
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:40:52
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User entered '4'	System	19 Mar 2021 18:40:52

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User entered '1'	System	19 Mar 2021 18:40:52

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:55
User entered '804 (804)'	System	19 Mar 2021 18:40:52

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 18:35:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 18:35:40
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:34:28 05 Apr 2021 18:34:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:28:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 18:44:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 18:44:43
Data point term sent to Coder User entered 'piperacillin/tazobactam'	System Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:43:25 19 Mar 2021 18:43:03

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Yes (Y)'	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:06:18
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:17:11
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:34:43
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:34:27
User entered 'CHOLECYSTECTOMY PRE OP' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	05 Apr 2021 18:34:27
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 06:59:21
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'pre op'	(b) (4) Jamie Pettus (b) (4) (b) (4)	19 Mar 2021 18:43:03



**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '2.25/3.375'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:43:03
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'g (g)'	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'four times daily (QID)'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:43:03
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Jamie Pettus (b) (4)	19 Mar 2021 18:43:03

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered empty.	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '22 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:43:03
	(b) (4)	



US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '0'	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered '22 Jan 2021'	(b) (4)	
	Jamie Pettus (b) (4)	19 Mar 2021 18:43:03
	(b) (4)	

US3752010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:28:27
User entered 'No (N)'	(b) (4)	19 Mar 2021 18:43:03
	Jamie Pettus (b) (4)	
	(b) (4)	

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User entered '4'	System	19 Mar 2021 18:43:03

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User entered '1'	System	19 Mar 2021 18:43:03

**US3752010**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:21:59
User entered '804 (804)'	System	19 Mar 2021 18:43:03

**US3752010**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:40:55**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:37:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 14:38:41
	Amanda Horn (b) (4)	
	(b) (4)	



US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered '22 Jan 2021'	Amanda Horn (b) (4)	27 Jan 2021 14:39:01
	(b) (4)	

**US3752010**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered 'CHOLECYSTECTOMY'	Amanda Horn (b) (4)	27 Jan 2021 14:39:01
	(b) (4)	

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 14:39:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 14:39:14
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Amanda Horn (b) (4)	27 Jan 2021 14:39:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 14:39:01
User entered empty.	Amanda Horn (b) (4)	27 Jan 2021 14:39:01
	(b) (4)	

**US3752010**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:01
	(b) (4)	
User entered empty.	Amanda Horn (b) (4)	27 Jan 2021 14:39:01
	(b) (4)	

**US3752010**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:46
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered '20 Jan 2021'	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:14
	(b) (4)	

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:40:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:46
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered 'ELECTROCARDIOGRAM'	Haylee Rowe (b) (4)	26 Apr 2021 13:48:14

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:46
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered 'Adverse Event (AE)'	Haylee Rowe (b) (4)	26 Apr 2021 13:48:14

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:40:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:46
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:14
	(b) (4)	



US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:53
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered '20 Jan 2021'	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:40
	(b) (4)	

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:40:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:53
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered 'ABDOMINAL ULTRASOUND'	Haylee Rowe (b) (4)	26 Apr 2021 13:48:40

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:53
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered 'Adverse Event (AE)'	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:40
	(b) (4)	

**US3752010**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:40:55**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:53
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:40
	(b) (4)	

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:05:06
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered '22 Jan 2021'	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:58
	(b) (4)	

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:40:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:05:06
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered 'ELECTROCARDIOGRAM'	Haylee Rowe (b) (4)	26 Apr 2021 13:48:58

**US3752010**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:05:06
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered 'Adverse Event (AE)'	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:58
	(b) (4)	

US3752010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:40:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:05:06
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered empty.	(b) (4)	
	Haylee Rowe (b) (4)	26 Apr 2021 13:48:58
	(b) (4)	



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered		
'USA-US113-2021-MRNA-1273-P301000004'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Priyantha'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Wijewardane'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered 'US'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 13:09:01
User entered '3'	System	22 Mar 2021 17:14:00
User entered '2'	System	22 Mar 2021 14:45:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered '1'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered		
'USA-US113-2021-MRNA-1273-P301000004'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Priyantha'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Wijewardane'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered 'US'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 13:09:01
User entered '3'	System	22 Mar 2021 17:14:00
User entered '2'	System	22 Mar 2021 14:45:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered '1'	System	28 Jan 2021 18:30:31



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered '28/Jan/2021 18:30'	System	28 Jan 2021 18:30:31

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:40:55

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'USA-US113-2021-MRNA-1273-P301000004'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Priyantha'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Wijewardane'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered 'US'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 13:09:01
User entered '3'	System	22 Mar 2021 17:14:00
User entered '2'	System	22 Mar 2021 14:45:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered '1'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	22 Mar 2021 23:38:33
	(b) (4)	
User entered '22/Mar/2021 10:45'	System	22 Mar 2021 14:45:25

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:40:55

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	22 Mar 2021 23:38:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:45:25



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'USA-US113-2021-MRNA-1273-P301000004'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Priyantha'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Wijewardane'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered 'US'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 13:09:01
User entered '3'	System	22 Mar 2021 17:14:00
User entered '2'	System	22 Mar 2021 14:45:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered '1'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	22 Mar 2021 23:38:33
	(b) (4)	
User entered '22/Mar/2021 13:13'	System	22 Mar 2021 17:14:00

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:40:55

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	22 Mar 2021 23:38:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:14:00

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'USA-US113-2021-MRNA-1273-P301000004'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Yes (Y)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'No (N)'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Priyantha'	System	28 Jan 2021 18:30:05

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 18:30:22
User entered 'Wijewardane'	System	28 Jan 2021 18:30:05



**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered 'US'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	27 Apr 2021 13:09:01
User entered '3'	System	22 Mar 2021 17:14:00
User entered '2'	System	22 Mar 2021 14:45:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 17:59:23
	(b) (4)	
User entered '1'	System	28 Jan 2021 18:30:31

**US3752010**

**Folder: SAE USA-US113-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
	(b) (4)	
User entered '27/Apr/2021 06:08'	System	27 Apr 2021 13:09:01

US3752010

Folder: SAE USA-US113-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:40:55

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	28 Apr 2021 03:46:21
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 13:09:01