

US3212250 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:49:32

All time stamps listed in this document are displayed in GMT

US3212250

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:27:07

Generated On: 09 Jun 2021 15:49:32

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Participant ID

US3212250

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

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US3212250

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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

Visit date (dd MMM yyyy)	19 AUG 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	SCRN
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US3212250

Folder: Screening

Form: Demographics

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 02 Apr 2021 21:27:31

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3212250

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	RENAL AGENESIS, LEFT SIDE
Start date (dd MMM yyyy)	(b) (6) 1945
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1945
Start Year (derived)	1945
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	BILATERAL CATARACTS
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	SHORTNESS OF BREATH
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	RECURRENT BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	HYSTERECTOMY
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 (10)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	WEDGE RESECTION OF RIGHT LUNG
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	UPPER LOBE LOBOTOMY, LEFT LUNG
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
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) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	BACK SURGERY
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	LUNG CANCER
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	BILATERAL CATARACT SURGERY
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)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	UTERINE FIBROIDS
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 (19)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	MORBID OBESITY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3212250

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2017
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	WATCHMAN IMPLANT
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018



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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	IODINE (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)	

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	PENICILLIN (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)	

US3212250

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	SULFA (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)	

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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	ASPIRIN HYPERSENSITIVITY
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)	

US3212250

Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	TRAMADOL 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)	

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Condition	URINARY INCONTINENCE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:01 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:01
Height ( <i>xxx.x</i> )	62 in
Weight ( <i>xxx.x</i> )	212.2 lb
BMI ( <i>xxx.x</i> )	38.89304 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) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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) 02 Apr 2021 21:27:31

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Date of assessment (dd MMM yyyy) 19 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 1977

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) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify** RETIRED

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

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

US3212250

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

<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)	False
<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>	True
<b>Specify</b>	PEOPLE IN THE PARTICIPANT'S WORKPLACE ARE NOT REGULARLY USING PERSONAL PROTECTION EQUIPMENT (MASKS, GLOVES, ETC). PARTICIPANT ATTENDED LARGE GROUP EVENTS IN THE PAST FEW WEEKS ...

US3212250

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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

Visit date (dd MMM yyyy)	19 AUG 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	VISIT1
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US3212250

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 186922

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☐   
 >=18 and <65 years and at risk ☐   
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Height	ND - Not Done
Weight	ND - Not Done

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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)	19 AUG 2020
Time of assessment (00:00-23:59)	13:01 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:01
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG



US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	16:19 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:19
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
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)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3212250

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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.*

US3212250

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 15:32 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 15:32

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

US3212250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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

Collection date (dd MMM yyyy)	19 AUG 2020
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Collection time (00:00-23:59)	14:56 (24 HR)
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Collection date and time (derived)	19 AUG 2020 14:56
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US3212250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Collection date ( <i>dd MMM yyyy</i> )			19 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:51	19 AUG 2020 14:51
Nasopharyngeal Swab 2	No		

US3212250

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

19 AUG 2020 16:11

PC Open Date & Time

19 AUG 2020 15:52

PC Close Date & Time

19 AUG 2020 18:22

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	19 AUG 2020 20:05
PC Open Date & Time	19 AUG 2020 19:17
PC Close Date & Time	20 AUG 2020 11:59



US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**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

97.8 °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

20 AUG 2020 18:17

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 18:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

22 AUG 2020 18:22

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**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

98.6 °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

23 AUG 2020 19:00

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 18:52

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**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

97.8 °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

25 AUG 2020 19:39

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**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

19 AUG 2020 16:12

PC Open Date & Time

19 AUG 2020 15:52

PC Close Date & Time

19 AUG 2020 18:22

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**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

19 AUG 2020 20:05

PC Open Date & Time

19 AUG 2020 19:17

PC Close Date & Time

20 AUG 2020 11:59



US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 18:17

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 18:06

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**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

22 AUG 2020 18:23

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**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

23 AUG 2020 19:01

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**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

24 AUG 2020 18:52

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**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

25 AUG 2020 19:39

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**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 ☐

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 16:13
PC Open Date & Time	19 AUG 2020 15:52
PC Close Date & Time	19 AUG 2020 18:22



US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**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 ☐

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 20:06
PC Open Date & Time	19 AUG 2020 19:17
PC Close Date & Time	20 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**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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US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:18
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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)

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 18:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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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US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:24
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59



US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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)

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:01
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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 ☒

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EAB) (1725)

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:53
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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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US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:40
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3212250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3212250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3212250

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:05
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)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 13:59
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3212250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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



US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 13:17 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 13:17

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

US3212250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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

Collection date (dd MMM yyyy)	16 SEP 2020
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Collection time (00:00-23:59)	13:14 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 SEP 2020 13:14
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US3212250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:10	16 SEP 2020 13:10
Nasopharyngeal Swab 2	No		

US3212250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 14:00

PC Open Date & Time

16 SEP 2020 13:37

PC Close Date & Time

16 SEP 2020 16:07

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**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 98.8 °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	16 SEP 2020 18:11
PC Open Date & Time	16 SEP 2020 17:02
PC Close Date & Time	17 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 18:47

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

18 SEP 2020 17:45

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59



US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 21:53

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.8 °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

21 SEP 2020 17:46

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**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

98.6 °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

22 SEP 2020 16:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**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

16 SEP 2020 14:01

PC Open Date & Time

16 SEP 2020 13:37

PC Close Date & Time

16 SEP 2020 16:07

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**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

16 SEP 2020 18:12

PC Open Date & Time

16 SEP 2020 17:02

PC Close Date & Time

17 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 18:48

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 17:46

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59



US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**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

19 SEP 2020 21:53

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**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

20 SEP 2020 20:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**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

21 SEP 2020 17:47

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**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

22 SEP 2020 16:37

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**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 ☐

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 14:02
PC Open Date & Time	16 SEP 2020 13:37
PC Close Date & Time	16 SEP 2020 16:07

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**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 ☐

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 18:13
PC Open Date & Time	16 SEP 2020 17:02
PC Close Date & Time	17 SEP 2020 11:59



US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**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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US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 18:49
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 17:46
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:54
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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)

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US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:57
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59



US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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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US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 17:48
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 16:37
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3212250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3212250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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

Visit date (dd MMM yyyy)	16 OCT 2020
--------------------------	-------------

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

Folder OID	VISIT3
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US3212250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 12:13
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3212250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

13:06 (24 HR)

Collection date and time (derived)

16 OCT 2020 13:06

US3212250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 15:49:36

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59



US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

26 OCT 2020 16:30:52

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

02 NOV 2020 09:37:03

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

16 NOV 2020 15:03:17

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 11:29:59
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 09:47:29

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

07 DEC 2020 11:01:11

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

14 DEC 2020 09:28:09

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 07:10:18
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59



US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

28 DEC 2020 09:22:01

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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 <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 09:47:25
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

11 JAN 2021 09:40:40

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

18 JAN 2021 09:22:29

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

25 JAN 2021 08:36:57

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 07:45:26

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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	08 FEB 2021 09:54:16
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

15 FEB 2021 06:57:27

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59



US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

22 FEB 2021 10:40:19

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 07:15:57

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

08 MAR 2021 10:17:29

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

15 MAR 2021 09:34:17

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

22 MAR 2021 05:55:26

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

29 MAR 2021 14:26:44

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

05 APR 2021 07:53:01

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

12 APR 2021 06:13:08

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59



US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

19 APR 2021 23:36:09

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

26 APR 2021 11:48:24

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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

03 MAY 2021 07:51:36

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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 <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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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 <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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59
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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JAN 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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°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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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°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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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°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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 607

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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°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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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26 JUL 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 733

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

---

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	16 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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°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 ☐



**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3212250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

**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 ☐

**US3212250**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

**US3212250**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 15:49:32**

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		08 MAR 2021 10:17:50

US3212250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3212250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:09

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:09

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:09

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:31

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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

Visit date (dd MMM yyyy)	16 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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US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 11:53
Temperature (xxx.x)	97.7 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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3212250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3212250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

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

Collection date (dd MMM yyyy)	16 MAR 2021
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Collection time (00:00-23:59)	12:33 (24 HR)
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Collection date and time (derived)	16 MAR 2021 12:33
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US3212250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3212250

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3212250**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

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*

**US3212250**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212250

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:49:32

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"/>



**US3212250**

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

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

**Generated On: 09 Jun 2021 15:49:32**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3212250

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:27:08

Generated On: 09 Jun 2021 15:49:32

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3212250

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 19:32:21

Generated On: 09 Jun 2021 15:49:32

Date of updated informed consent (dd MMM yyyy) 19 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) 19 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 \_\_\_\_\_

US3212250

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:27:08

Generated On: 09 Jun 2021 15:49:32

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 19 JAN 2021

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

Collection date and time (derived) 19 JAN 2021 11:59

US3212250

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:27:08

Generated On: 09 Jun 2021 15:49:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	11:22
Collection Date and Time (derived)	19 JAN 2021 11:22

US3212250

Folder: **Unscheduled 13 Nov 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Visit Date	13 NOV 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3212250

Folder: Unscheduled 13 Nov 2020

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:27:32

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	13:55 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 13:55
Temperature ( <i>xxx.x</i> )	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212250

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 02 Apr 2021 21:27:07

Generated On: 09 Jun 2021 15:49:32

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3212250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

CHEST CONTUSION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

US3212250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:49:32

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

US3212250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

LEFT AC JOINT SORENESS

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)

17 SEP 2020

Start time (00:00-23:59)

15:00 (24 HR)

AE start date and time (derived)

17 SEP 2020 15:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 JAN 2021

End time (00:00-23:59)

16:30 (24 HR)

AE End Date and Time (derived)

1 JAN 2021 16:30

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

BURSITIS OF LEFT SHOULDER

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)

03 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

US3212250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

OSTEOARTHRITIS OF LEFT  
SHOULDER

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)

03 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

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



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

LEFT ROTATOR CUFF STRAIN

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)

03 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

FALL

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)

07 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy)

07 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐  
Grade 2/Moderate ☒  
Grade 3/Severe ☐  
Grade 4 ☐

Is the adverse event serious?

Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐  
No ☐  
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

FRACTURED RIGHT ELBOW

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)

07 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:49:32

AEID	USA-US115-2021-MRNA-1273-P30 1000013
Adverse event	COLOVESCIAL FISTULA
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)	11 FEB 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)	5 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	12 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:49:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	SUBJECT ADMITTED ON 2/11/21 FOR UTI AND SEPSIS DUE TO COLONIC FISTULA. DISCHARGED WITH ORAL COURSE OF ANTIBIOTICS 2/12/21.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒  
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐  
No ☒

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

Yes ☐  
No ☒

Start date (dd MMM yyyy)

07 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy)

11 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐  
Grade 2/Moderate ☒  
Grade 3/Severe ☐  
Grade 4 ☐

Is the adverse event serious?

Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐  
No ☐  
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

FRACTURED RIGHT THUMB

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)

07 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3212250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

FRACTURED RIGHT RIB

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)

07 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:49:32

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

FRACTURED LEFT RIB

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)

07 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:49:32

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:49:32

AEID

Adverse event

WORSENING HYPERTENSION

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)

04 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:49:32

Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input 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)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

AEID	USA-US115-2021-MRNA-1273-P30 1000013
Adverse event	COLOVESICULAR FISTULA (SIGMOID COLECTOMY SURGERY)
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)	5 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 APR 2021
Hospital Discharge Date (dd MMM yyyy)	8 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

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SHE REPORTS AN INPATIENT  
ADMISSION AND SURGERY OF  
SIGMOID COLECTOMY FOR  
COLOVESICIAL FISTULA ON  
04APRIL2021. SHE REMAINED  
HOSPITALIZED FOR RECOVERY  
UNTIL 08APRIL2021 AFTER  
WHICH SHE WAS  
TRANSFERRED TO INPATIENT  
REHAB. HOSPITALIZATION  
OCCURRED AT HCA CLEAR  
LAKE REGIONAL MEDICAL  
CENTER. SUBJECT HAS  
SEVERAL NEW MEDICATIONS  
BUT DOES NOT REMEMBER  
THE NAMES AND DOSAGES.  
MEDICAL RECORDS HAVE  
BEEN REQUESTED AND  
MEDICATION LIST WILL BE  
UPDATED ACCORDINGLY  
AFTER CHART REVIEW.

---

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

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US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:27:08

Generated On: 09 Jun 2021 15:49:32

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

Yes ☒

No ☐

---

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

---



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	4 MAR 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"/>

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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 (2)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒  
No ☐

Indication IMMUNIZATION

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	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)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication LEFT AC JOINT SORENESS

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 (4)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	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)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 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"/>



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication TIZANIDINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT AC JOINT SORENESS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication LEFT AC JOINT SORENESS

Dose per administration 15

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 (6)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication BURSITIS OF LEFT SHOULDER

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRA-ARTICULAR	
Start date (dd MMM yyyy)	03 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☐  
No ☒

Indication BURSITIS OF LEFT SHOULDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRA-ARTICULAR	
Start date (dd MMM yyyy)	03 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication TYLENOL 3  
(CODEINE/ACETAMINOPHEN)

Prophylaxis Yes ☐  
No ☒

Indication FRACTURED RIGHT ELBOW

Dose per administration 30/300

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	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)	07 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (10)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication CEFDINIR

Prophylaxis Yes ☐  
No ☒

Indication COLONIC FISTULA

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 FEB 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 (12)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING HYPERTENSION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 18:48:02

Generated On: 09 Jun 2021 15:49:32

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



US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:27:08

Generated On: 09 Jun 2021 15:49:32

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 19:13:23

Generated On: 09 Jun 2021 15:49:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 FEB 2021	X-RAY OF RIGHT UPPER EXTREMITY	Adverse Event	
07 FEB 2021	CT SCAN OF HEAD	Adverse Event	
5 APR 2021	SIGMOID COLECTOMY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:49:32

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

US3212250

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:49:32

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 ☐

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/FEB/2021 10:22
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

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/FEB/2021 10:31
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

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/FEB/2021 07:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	06/APR/2021 06:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	07/APR/2021 08:37
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

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (6)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	14/APR/2021 13:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (7)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	20/APR/2021 08:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (8)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/APR/2021 11:59
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

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (9)

Data signed: (b) (4) 01 May 2021 18:40:47

Generated On: 09 Jun 2021 15:49:32

SAEID	USA-US115-2021-MRNA-1273-P301000013
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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	30/APR/2021 12:15
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

US3212250 (Prod: DM Clinical Research - ERN - PPDS)

**US3212250**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:49:32**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'US3212250'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:11



US3212250

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:49:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:46:56

US3212250

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:49:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:13

**US3212250**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	19 Aug 2020 19:46:56

**US3212250**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'SCRN'	System	19 Aug 2020 19:46:56

US3212250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:49:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:14

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '75'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'YEARS'	System	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '75'	System	19 Aug 2020 19:47:19



**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Female (F)'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'I'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08



**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

**US3212250**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:49:32**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:08

US3212250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:49:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:19

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Aug 2020'	System	19 Aug 2020 19:47:19

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2020'	System	19 Aug 2020 19:47:19

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Amendment 2 (2)'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:19

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:19



**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 19:47:19

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 19:47:19

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:19

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:13

**US3212250**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:49:32**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'I'	System	19 Aug 2020 19:47:25

**US3212250**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:25

**US3212250**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 15:49:32**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:47:35

US3212250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Renal and urinary tract disorders congenital, HLT: Renal disorders congenital, PT: Renal aplasia, LLT: Unilateral renal agenesis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 13:07:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 13:07:29
Data point term sent to Coder	System	20 Aug 2020 02:35:29
User entered 'Renal Agenesis, Left Side'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:26



US3212250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:49:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		20 Aug 2020 02:40:15
User entered (b) (6) 1945' reason for change: Data Afifah Ayub (b) (4) Entry Error	(b) (4)	20 Aug 2020 02:40:15
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	20 Aug 2020 02:35:26
User entered 'UN UNK 1945'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:26
	(b) (4)	

**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:26

**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:26

**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:35:26

**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:26

**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered (b) (6) 1945'	System	20 Aug 2020 02:40:15
User entered 'Jan 1945'	System	20 Aug 2020 02:35:26

**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1945'	System	20 Aug 2020 02:35:26

**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:35:26



**US3212250**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:35:26

US3212250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Aug 2020 02:37:12
Data point term sent to Coder	System	20 Aug 2020 02:36:31
User entered 'Bilateral Cataracts'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:43
	(b) (4)	

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1995'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:43

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:43

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:43

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2019'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:43

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:43

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1995'	System	20 Aug 2020 02:35:43



**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1995'	System	20 Aug 2020 02:35:43

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2019'	System	20 Aug 2020 02:35:43

**US3212250**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2019'	System	20 Aug 2020 02:35:43

US3212250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:13
Data point term sent to Coder	System	20 Aug 2020 02:36:30
User entered 'Bilateral Tinnitus'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1990'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:35:56



**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1990'	System	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1990'	System	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:35:56

**US3212250**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:35:56

US3212250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:12
Data point term sent to Coder	System	20 Aug 2020 02:36:32
User entered 'Seasonal Allergies'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:06



**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2000'	System	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2000'	System	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:36:06

**US3212250**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:36:06

US3212250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:12
Data point term sent to Coder	System	20 Aug 2020 02:36:29
User entered 'Shortness of breath'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:18



**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2007'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:18

**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:18

**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:18

**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:36:18

**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:18

**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2007'	System	20 Aug 2020 02:36:18

**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2007'	System	20 Aug 2020 02:36:18

**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:36:18



**US3212250**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:36:18

US3212250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:37:12
Data point term sent to Coder	System	20 Aug 2020 02:36:32
User entered 'Hypertension'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1965'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1965'	System	20 Aug 2020 02:36:30



**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1965'	System	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:36:30

**US3212250**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:36:30

US3212250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:38:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:38:13
Data point term sent to Coder	System	20 Aug 2020 02:37:32
User entered 'Transient Ischemic Attack'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2010'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2010'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:48



**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2010'	System	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2010'	System	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2010'	System	20 Aug 2020 02:36:48

**US3212250**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2010'	System	20 Aug 2020 02:36:48

US3212250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:38:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:38:13
Data point term sent to Coder	System	20 Aug 2020 02:37:32
User entered 'Recurrent Back pain'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:03

US3212250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:49:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	20 Aug 2020 14:06:34
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	20 Aug 2020 14:06:34
User entered 'UN UNK 1989' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 14:06:34
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	20 Aug 2020 02:37:03
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	20 Aug 2020 02:37:03
User entered 'UN UNK 2989'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:03

**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:03



**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:03

**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:37:03

**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:03

**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1989'	System	20 Aug 2020 14:06:34
User entered 'Jan 2989'	System	20 Aug 2020 02:37:03

**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1989'	System	20 Aug 2020 14:06:34
User entered '2989'	System	20 Aug 2020 02:37:03

**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:37:03

**US3212250**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	20 Aug 2020 02:37:03

US3212250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
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)	20 Aug 2020 02:38:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:38:13
Data point term sent to Coder	System	20 Aug 2020 02:37:33
User entered 'Hysterectomy'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:23



**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1977'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:23

**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:23

**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:23

**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1977'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:23

**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:23

**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1977'	System	20 Aug 2020 02:37:23

**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1977'	System	20 Aug 2020 02:37:23

**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1977'	System	20 Aug 2020 02:37:23



**US3212250**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1977'	System	20 Aug 2020 02:37:23

US3212250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric banding, LLT: Gastric banding - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:39:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:39:15
Data point term sent to Coder	System	20 Aug 2020 02:38:36
User entered 'Gastric Banding'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2010'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2010'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2010'	System	20 Aug 2020 02:37:36



**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2010'	System	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2010'	System	20 Aug 2020 02:37:36

**US3212250**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2010'	System	20 Aug 2020 02:37:36

US3212250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Bronchial and pulmonary therapeutic procedures, PT: Pulmonary resection, LLT: Lung wedge resection - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 05:53:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 05:53:19
Data point term sent to Coder	System	20 Aug 2020 02:38:34
User entered 'Wedge Resection of Right Lung'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2007'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2007'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:50



**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2007'	System	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2007'	System	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2007'	System	20 Aug 2020 02:37:50

**US3212250**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2007'	System	20 Aug 2020 02:37:50

US3212250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Bronchial and pulmonary therapeutic procedures, PT: Lung lobectomy, LLT: Lung lobectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 05:55:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 05:55:17
Data point term sent to Coder	System	20 Aug 2020 02:38:34
User entered 'Upper lobe lobotomy, Left Lung'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2011'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:03



**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2011'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2011'	System	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2011'	System	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2011'	System	20 Aug 2020 02:38:03

**US3212250**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2011'	System	20 Aug 2020 02:38:03

US3212250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
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)	13 Oct 2020 20:17:36
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 'As recorded # 8, Recurrent back Pain already captured' (Site from DM).	Afifah Ayub (b) (4)	21 Sep 2020 20:07:59
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)	10 Sep 2020 10:26:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:39:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:39:15
Data point term sent to Coder	System	20 Aug 2020 02:38:36
User entered 'Back surgery'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:16



**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2018'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:16

**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:16

**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:16

**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2018'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:16

**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:16

**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2018'	System	20 Aug 2020 02:38:16

**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2018'	System	20 Aug 2020 02:38:16

**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2018'	System	20 Aug 2020 02:38:16



**US3212250**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2018'	System	20 Aug 2020 02:38:16

US3212250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Respiratory tract and pleural neoplasms malignant cell type unspecified NEC, PT: Lung neoplasm malignant, LLT: Lung cancer - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:39:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:39:15
Data point term sent to Coder	System	20 Aug 2020 02:38:36
User entered 'Lung Cancer'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2007'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2011'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2007'	System	20 Aug 2020 02:38:29



**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2007'	System	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2011'	System	20 Aug 2020 02:38:29

**US3212250**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2011'	System	20 Aug 2020 02:38:29

US3212250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
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)	13 Oct 2020 20:18:07
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 'Subject's elbow surgery was due to an elbow injury she had in 2002. Year was listed incorrectly previously. Medical History was updated accordingly' (Site from DM).	Afifah Ayub (b) (4)	22 Sep 2020 21:38:24
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)	10 Sep 2020 10:27:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Elbow operation, LLT: Elbow operation - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 02:40:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 02:40:25
Data point term sent to Coder	System	20 Aug 2020 02:39:37
User entered 'Right Elbow Surgery'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2001'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2001'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:52



**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2001'	System	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2001'	System	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2001'	System	20 Aug 2020 02:38:52

**US3212250**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2001'	System	20 Aug 2020 02:38:52

US3212250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:59:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:40:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:40:26
Data point term sent to Coder	System	20 Aug 2020 02:39:38
User entered 'Bilateral cataract Surgery'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2019'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:05



**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2019'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2019'	System	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2019'	System	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2019'	System	20 Aug 2020 02:39:05

**US3212250**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2019'	System	20 Aug 2020 02:39:05

US3212250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Elbow injury - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:40:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:40:26
Data point term sent to Coder	System	20 Aug 2020 02:39:37
User entered 'Right Elbow Injury'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:18



US3212250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2001' reason for change: Data Entry Error	Afifah Ayub (b) (4)	22 Sep 2020 21:38:53
User entered 'UN UNK 2019'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:18

**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:18

**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:18

**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2001' reason for change: Data Entry Error	Afifah Ayub (b) (4)	22 Sep 2020 21:38:53
User entered 'UN UNK 2019'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:18

**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:18

**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2001'	System	22 Sep 2020 21:38:53
User entered 'Jan 2019'	System	20 Aug 2020 02:39:18

**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2001'	System	22 Sep 2020 21:38:53
User entered '2019'	System	20 Aug 2020 02:39:18

**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2001'	System	22 Sep 2020 21:38:53
User entered 'Jan 2019'	System	20 Aug 2020 02:39:18



**US3212250**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2001'	System	22 Sep 2020 21:38:53
User entered '2019'	System	20 Aug 2020 02:39:18

US3212250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:41:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 02:41:12
Data point term sent to Coder	System	20 Aug 2020 02:40:38
User entered 'Uterine Fibroids'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1977'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1977'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1977'	System	20 Aug 2020 02:39:39



**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1977'	System	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 1977'	System	20 Aug 2020 02:39:39

**US3212250**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '1977'	System	20 Aug 2020 02:39:39

US3212250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 02:41:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 02:41:12
Data point term sent to Coder	System	20 Aug 2020 02:40:38
User entered 'Morbid Obesity'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 2010'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:56



**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2000'	System	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2000'	System	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2010'	System	20 Aug 2020 02:39:56

**US3212250**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2010'	System	20 Aug 2020 02:39:56

US3212250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:02:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:02:44
Data point term sent to Coder	System	17 Sep 2020 17:01:24
User entered 'Insomnia'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN Mar 2020'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:28



**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Mar 2020'	System	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2020'	System	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	17 Sep 2020 17:00:28

**US3212250**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	17 Sep 2020 17:00:28

US3212250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Neck strain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 11:23:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 11:23:49
Data point term sent to Coder	System	17 Sep 2020 17:01:24
User entered 'neck strain, intermittent'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:38



**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Un Mar 2020'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:38

**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:38

**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:38

**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:00:38

**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:00:38

**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Mar 2020'	System	17 Sep 2020 17:00:38

**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2020'	System	17 Sep 2020 17:00:38

**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	17 Sep 2020 17:00:38



**US3212250**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	17 Sep 2020 17:00:38

US3212250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 19:28:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:28:54
Data point term sent to Coder	System	14 Apr 2021 19:28:32
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	14 Apr 2021 19:28:18

**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:28:18

**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:28:18

US3212250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:49:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Apr 2021 19:28:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 19:28:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 19:28:26
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 19:28:18
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:28:18

**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:28:18

**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:28:18

**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2016'	System	14 Apr 2021 19:28:18



**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2016'	System	14 Apr 2021 19:28:18

**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2017'	System	14 Apr 2021 19:28:18

**US3212250**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2017'	System	14 Apr 2021 19:28:18

US3212250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Apr 2021 19:29:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:29:57
Data point term sent to Coder	System	14 Apr 2021 19:29:33
User entered 'diverticulosis'	(b) (4), (b) (6)	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:29:12



**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2016'	System	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2016'	System	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:29:12

**US3212250**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:29:12

US3212250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
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) Coder Import (b) (4)	14 Apr 2021 19:30:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:30:56
Data point term sent to Coder	System	14 Apr 2021 19:30:34
User entered 'atrial fibrillation'	(b) (4), (b) (6)	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:29:54



**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2017'	System	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2017'	System	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2018'	System	14 Apr 2021 19:29:54

**US3212250**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2018'	System	14 Apr 2021 19:29:54

US3212250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Medical device implantation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Apr 2021 09:52:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:52:47
Data point term sent to Coder	System	14 Apr 2021 19:30:34
User entered 'Watchman Implant'	(b) (4), (b) (6)	14 Apr 2021 19:30:31



**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:30:31

**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:30:31

**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:30:31

**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:30:31

**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:30:31

**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2018'	System	14 Apr 2021 19:30:31

**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2018'	System	14 Apr 2021 19:30:31

**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2018'	System	14 Apr 2021 19:30:31



**US3212250**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2018'	System	14 Apr 2021 19:30:31

US3212250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Apr 2021 19:32:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:32:02
Data point term sent to Coder	System	14 Apr 2021 19:31:35
User entered 'Right Shoulder Pain'	(b) (4), (b) (6)	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2003'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2003'	System	14 Apr 2021 19:31:08



**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2003'	System	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:31:08

**US3212250**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:31:08

US3212250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Iodine allergy, LLT: Iodine allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Apr 2021 09:28:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:28:44
Data point term sent to Coder	System	14 Apr 2021 19:32:37
User entered 'Iodine (Allergy)'	(b) (4), (b) (6)	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:32:08



**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:08

**US3212250**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:08

US3212250

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
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: Penicillin allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 19:35:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:35:05
Data point term sent to Coder	System	14 Apr 2021 19:33:39
User entered 'Penicillin (Allergy)'	(b) (4), (b) (6)	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 19:32:44



**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:44

**US3212250**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:32:44

US3212250

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 15:49:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
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: Sulfonamide allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Apr 2021 19:35:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:35:05
Data point term sent to Coder	System	14 Apr 2021 19:33:39
User entered 'Sulfa (Allergy)'	(b) (4), (b) (6)	14 Apr 2021 19:33:09



**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:33:09

**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 19:33:09

**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:33:09

**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:33:09

**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:33:09

**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:09

**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:09

**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:09



**US3212250**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:09

US3212250

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
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 hypersensitivity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Apr 2021 15:21:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 15:21:11
Data point term sent to Coder	(b) (4)	15 Apr 2021 14:34:35
User closed query 'CDM Coding : Please clarify if this refers to ASPIRIN SENSITIVITY (eg. DRUG INTOLERANCE or DRUG ALLERGY or DRUG HYPERSENSITIVITY,etc) and update the term in the verbatim text field. Thank you.' (Site from System).	System	15 Apr 2021 14:33:49
Query 'CDM Coding : Please clarify if this refers to ASPIRIN SENSITIVITY (eg. DRUG INTOLERANCE or DRUG ALLERGY or DRUG HYPERSENSITIVITY,etc) and update the term in the verbatim text field. Thank you.' answered with 'updated' (Site from System).	Heather Leary (b) (4)	15 Apr 2021 14:33:49
Data point term sent to Coder	(b) (4)	15 Apr 2021 14:33:34
User entered 'ASPIRIN HYPERSENSITIVITY' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Apr 2021 14:33:33
User opened query 'CDM Coding : Please clarify if this refers to ASPIRIN SENSITIVITY (eg. DRUG INTOLERANCE or DRUG ALLERGY or DRUG HYPERSENSITIVITY,etc) and update the term in the verbatim text field. Thank you.' (Site from System).	(b) (4) Coder Import (b) (4)	15 Apr 2021 09:23:45
Data point term sent to Coder	System	14 Apr 2021 19:34:41
User entered 'Aspirin Sensitivity'	(b) (4), (b) (6)	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:44



**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:44

**US3212250**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:33:44

US3212250

Folder: Screening

Form: Medical History (31)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
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: Allergic reaction to analgesics - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 19:35:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 19:35:56
Data point term sent to Coder	System	14 Apr 2021 19:34:40
User entered 'tramadol allergy'	(b) (4), (b) (6)	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:34:14



**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:34:14

**US3212250**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:34:14

US3212250

Folder: Screening

Form: Medical History (32)

Generated On: 09 Jun 2021 15:49:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Apr 2021 19:37:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:37:08
Data point term sent to Coder	(b) (4)	14 Apr 2021 19:35:43
User entered 'urinary incontinence'	System (b) (4), (b) (6)	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:34:53



**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'Jan 2016'	System	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '2016'	System	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:34:53

**US3212250**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered empty.	System	14 Apr 2021 19:34:53

US3212250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16



US3212250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:01'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered '19 Aug 2020 13:01'	System	19 Aug 2020 19:49:16

US3212250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '62' in	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16
DataPoint set to visible.	(b) (4) System	19 Aug 2020 19:47:25

US3212250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '212.2' lb	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16
DataPoint set to visible.	(b) (4) System	19 Aug 2020 19:47:25

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
Amendment Manager: User entered '38.89304'	System	17 Sep 2020 00:14:52
User entered '38.9'	System	19 Aug 2020 19:49:16
DataPoint set to visible.	System	19 Aug 2020 19:47:25

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'kg/m2'	System	19 Aug 2020 19:49:16
DataPoint set to visible.	System	19 Aug 2020 19:47:25

US3212250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16



**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 19:12:55
User entered 'Other (Other)'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 19:12:55
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'bpm'	System	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'breaths/min'	System	19 Aug 2020 19:49:16

US3212250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'mmHg'	System	19 Aug 2020 19:49:16



US3212250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User entered 'mmHg'	System	19 Aug 2020 19:49:16

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54

**US3212250**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54

US3212250

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:49:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:27

US3212250

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:49:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 16:48:54
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		16 Sep 2020 18:32:42
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:27

**US3212250**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:49:32**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53

US3212250

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:49:32

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53



**US3212250**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:49:32**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Surgically sterile (SURGICALLY STERILE)'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53

**US3212250**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:49:32**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53

US3212250

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'UN UNK 1977'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53

**US3212250**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:49:32**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53

US3212250

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53

**US3212250**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:49:32**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:49:53

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40



US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

[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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40



US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Retired'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

**US3212250**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:49:32**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

**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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

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)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40



US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'I'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

US3212250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:49:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:05:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'People in the participant's workplace are not regularly using personal protection equipment (masks, gloves, etc). Participant attended large group events in the past few weeks ...'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:40

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:50

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:50

US3212250

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:49:32

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 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	19 Aug 2020 19:50:50

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'VISIT1'	System	19 Aug 2020 19:50:50

US3212250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:30



US3212250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:49:32

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:41:54
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:41:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 19:44:30
User entered '186922' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:30

US3212250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:49:32

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:30

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:49:32**

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)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:31:36

US3212250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:49:32

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)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:31:36

US3212250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:49:32

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:31:36

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:49:32**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:31:36

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:49:32**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	20 Aug 2020 02:31:36

US3212250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:49:32

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:37:04



US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:49:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:49:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:49:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:49:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:01'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08



**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '19 Aug 2020 13:01'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '97.8' F	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '80'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'bpm'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'breaths/min'	System	20 Aug 2020 02:34:08



US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '138'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '86'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:49:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:49:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08



US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
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) (6)	20 Aug 2020 18:44:02
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'As per protocol, post-dose vitals are done at 30 minutes.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:16
' (Site from System).		
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).		20 Aug 2020 02:34:08
User entered '16:19'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '19 Aug 2020 16:19'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '97.5' F	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '70'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'bpm'	System	20 Aug 2020 02:34:08



US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'breaths/min'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '129'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '75'	Afifah Ayub (b) (4)	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	20 Aug 2020 02:34:08

US3212250

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 19:52:19

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:49:32**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 19:52:19



US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 20:33:29

US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 20:33:29

US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

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)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 20:33:29

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:49:32**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:33:29

US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 20:33:29

US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '15:32'	Afifah Ayub (b) (4)	19 Aug 2020 20:33:29

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:49:32**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '19 Aug 2020 15:32'	System	19 Aug 2020 20:33:29

US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	19 Aug 2020 20:33:29



US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'ONCE'	System	19 Aug 2020 20:33:29

US3212250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:33:29

US3212250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:42

US3212250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:42

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '14:56'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:42

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '19 Aug 2020 14:56'	System	19 Aug 2020 21:58:42

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 15:49:32**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '19 Aug 2020'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:55

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	19 Aug 2020 21:58:55



US3212250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:49:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:55

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:49:32**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '14:51'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:55

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '19 Aug 2020 14:51'	System	19 Aug 2020 21:58:55

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	19 Aug 2020 21:58:55

US3212250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:49:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 21:58:15
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:55

US3212250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:49:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 21:58:15
User entered '14:51'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:55

**US3212250**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered empty.	System	25 Aug 2020 21:58:15
User entered '19 Aug 2020 14:51'	System	19 Aug 2020 21:58:55

US3212250

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 21:58:30



**US3212250**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'I'	System	19 Aug 2020 21:58:30

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:10:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf0c94f1-4540-4386-a412-dbf128e8f2c0' User entered 'Yes (Y)'	System	19 Aug 2020 21:11:19
	System	19 Aug 2020 21:11:19

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:11:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf0c94f1-4540-4386-a412-dbf128e8f2c0' User entered '97.5'	System	19 Aug 2020 21:11:19
	System	19 Aug 2020 21:11:19

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:11:10', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf0c94f1-4540-4386-a412-dbf128e8f2c0'	System	19 Aug 2020 21:11:19
User entered 'No (N)'	System	19 Aug 2020 21:11:19

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:11:18', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf0c94f1-4540-4386-a412-dbf128e8f2c0' User entered '19 Aug 2020 16:11'	System	19 Aug 2020 21:11:19
	System	19 Aug 2020 21:11:19

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 15:52'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 18:22'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:04:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd8780ae7-6acd-44a1-a278-ad9339f8c477'	System	20 Aug 2020 01:05:22
User entered 'Yes (Y)'	System	20 Aug 2020 01:05:22

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:07', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd8780ae7-6acd-44a1-a278-ad9339f8c477'	System	20 Aug 2020 01:05:22
User entered '97.9'	System	20 Aug 2020 01:05:22

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:12', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd8780ae7-6acd-44a1-a278-ad9339f8c477'	System	20 Aug 2020 01:05:22
User entered 'No (N)'	System	20 Aug 2020 01:05:22

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:19', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd8780ae7-6acd-44a1-a278-ad9339f8c477'	System	20 Aug 2020 01:05:22
User entered '19 Aug 2020 20:05'	System	20 Aug 2020 01:05:22

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 19:17'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 2'	System	19 Aug 2020 20:33:29



US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:16:24', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cc60c644-4353-447e-90aa-171c6abf2a39'	System	20 Aug 2020 23:17:11
User entered 'Yes (Y)'	System	20 Aug 2020 23:17:11

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:16:53', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cc60c644-4353-447e-90aa-171c6abf2a39' User entered '97.8'	System	20 Aug 2020 23:17:11
	System	20 Aug 2020 23:17:11

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:16:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cc60c644-4353-447e-90aa-171c6abf2a39'	System	20 Aug 2020 23:17:11
User entered 'No (N)'	System	20 Aug 2020 23:17:11

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:07', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cc60c644-4353-447e-90aa-171c6abf2a39'	System	20 Aug 2020 23:17:11
User entered '20 Aug 2020 18:17'	System	20 Aug 2020 23:17:11

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 3'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:06:59', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'dedea9fc-bbbc-42d4-94d6-bff708f6fc04'	System	21 Aug 2020 23:07:39
User entered 'Yes (Y)'	System	21 Aug 2020 23:07:39



US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:07:31', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'dedea9fc-bbbc-42d4-94d6-bff708f6fc04' User entered '98.3'	System	21 Aug 2020 23:07:39
	System	21 Aug 2020 23:07:39

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:07:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'dedea9fc-bbbc-42d4-94d6-bff708f6fc04'	System	21 Aug 2020 23:07:39
User entered 'No (N)'	System	21 Aug 2020 23:07:39

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:07:37', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'dedea9fc-bbbc-42d4-94d6-bff708f6fc04' User entered '21 Aug 2020 18:07'	System	21 Aug 2020 23:07:39
	System	21 Aug 2020 23:07:39

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 4'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:22:11', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e067dd-8655-4819-b16a-1a6f1cd788a1' User entered 'Yes (Y)'	System	22 Aug 2020 23:22:29
	System	22 Aug 2020 23:22:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:22:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e067dd-8655-4819-b16a-1a6f1cd788a1' User entered '98.6'	System	22 Aug 2020 23:22:29
	System	22 Aug 2020 23:22:29



US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:22:21', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e067dd-8655-4819-b16a-1a6f1cd788a1' User entered 'No (N)'	System	22 Aug 2020 23:22:29
	System	22 Aug 2020 23:22:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:22:27', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e067dd-8655-4819-b16a-1a6f1cd788a1' User entered '22 Aug 2020 18:22'	System	22 Aug 2020 23:22:29
	System	22 Aug 2020 23:22:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 5'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:00:30', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '41738a08-6251-4fed-a8d1-00b89e56eac9'	System	24 Aug 2020 00:00:50
User entered 'Yes (Y)'	System	24 Aug 2020 00:00:50

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:00:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '41738a08-6251-4fed-a8d1-00b89e56eac9' User entered '98.6'	System	24 Aug 2020 00:00:50
	System	24 Aug 2020 00:00:50

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:00:41', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '41738a08-6251-4fed-a8d1-00b89e56eac9'	System	24 Aug 2020 00:00:50
User entered 'No (N)'	System	24 Aug 2020 00:00:50



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:00:46', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '41738a08-6251-4fed-a8d1-00b89e56eac9'	System	24 Aug 2020 00:00:50
User entered '23 Aug 2020 19:00'	System	24 Aug 2020 00:00:50

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 6'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8eaf0bee-8105-44ab-abcb-0644568bd8b0' User entered 'Yes (Y)'	System	24 Aug 2020 23:52:28
	System	24 Aug 2020 23:52:28

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8eaf0bee-8105-44ab-abcb-0644568bd8b0' User entered '98.7'	System	24 Aug 2020 23:52:28
	System	24 Aug 2020 23:52:28

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:19', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8eaf0bee-8105-44ab-abcb-0644568bd8b0'	System	24 Aug 2020 23:52:28
User entered 'No (N)'	System	24 Aug 2020 23:52:28

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:23', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8eaf0bee-8105-44ab-abcb-0644568bd8b0' User entered '24 Aug 2020 18:52'	System	24 Aug 2020 23:52:28
	System	24 Aug 2020 23:52:28



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 7'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:38:56', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8ce2c243-1ff4-4b0f-bbcb-23a6c5dcf8db' User entered 'Yes (Y)'	System	26 Aug 2020 00:39:36
	System	26 Aug 2020 00:39:36

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8ce2c243-1ff4-4b0f-bbcb-23a6c5dcf8db' User entered '97.8'	System	26 Aug 2020 00:39:36
	System	26 Aug 2020 00:39:36

US3212250

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:11', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8ce2c243-1ff4-4b0f-bbcb-23a6c5dcf8db'	System	26 Aug 2020 00:39:36
User entered 'No (N)'	System	26 Aug 2020 00:39:36

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8ce2c243-1ff4-4b0f-bbcb-23a6c5dcf8db' User entered '25 Aug 2020 19:39'	System	26 Aug 2020 00:39:36
	System	26 Aug 2020 00:39:36

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:11:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8e57214-a944-4422-a176-7bfa64e4d99'	System	19 Aug 2020 21:12:18
User entered 'None (1)'	System	19 Aug 2020 21:12:18

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:11:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8e57214-a944-4422-a176-7bfa64e4d99'	System	19 Aug 2020 21:12:18
User entered 'No (N)'	System	19 Aug 2020 21:12:18

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:11:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8e57214-a944-4422-a176-7bfa64e4d99'	System	19 Aug 2020 21:12:18
User entered 'No (N)'	System	19 Aug 2020 21:12:18

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:12:07', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8e57214-a944-4422-a176-7bfa64e4d99'	System	19 Aug 2020 21:12:18
User entered 'None (1)'	System	19 Aug 2020 21:12:18

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:12:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8e57214-a944-4422-a176-7bfa64e4d99'	System	19 Aug 2020 21:12:18
User entered '19 Aug 2020 16:12'	System	19 Aug 2020 21:12:18

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 15:52'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 18:22'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c578cbd0-3f76-4e21-be35-85d2de48dc2c' User entered 'None (1)'	System	20 Aug 2020 01:05:56
	System	20 Aug 2020 01:05:56

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:33', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c578cbd0-3f76-4e21-be35-85d2de48dc2c' User entered 'No (N)'	System	20 Aug 2020 01:05:56
	System	20 Aug 2020 01:05:56

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:37', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c578cbd0-3f76-4e21-be35-85d2de48dc2c' User entered 'No (N)'	System	20 Aug 2020 01:05:56
	System	20 Aug 2020 01:05:56

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:45', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c578cbd0-3f76-4e21-be35-85d2de48dc2c' User entered 'None (1)'	System	20 Aug 2020 01:05:56
	System	20 Aug 2020 01:05:56

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:05:53', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c578cbd0-3f76-4e21-be35-85d2de48dc2c' User entered '19 Aug 2020 20:05'	System	20 Aug 2020 01:05:56
	System	20 Aug 2020 01:05:56

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 19:17'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 2'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:13', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf2e392b-747a-4bd7-9961-650c2b3f47c5'	System	20 Aug 2020 23:17:40
User entered 'None (1)'	System	20 Aug 2020 23:17:40

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf2e392b-747a-4bd7-9961-650c2b3f47c5'	System	20 Aug 2020 23:17:40
User entered 'No (N)'	System	20 Aug 2020 23:17:40

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:20', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf2e392b-747a-4bd7-9961-650c2b3f47c5' User entered 'No (N)'	System	20 Aug 2020 23:17:40
	System	20 Aug 2020 23:17:40

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:27', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf2e392b-747a-4bd7-9961-650c2b3f47c5'	System	20 Aug 2020 23:17:40
User entered 'None (1)'	System	20 Aug 2020 23:17:40

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'cf2e392b-747a-4bd7-9961-650c2b3f47c5' User entered '20 Aug 2020 18:17'	System	20 Aug 2020 23:17:40
	System	20 Aug 2020 23:17:40

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 3'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:06:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '04f25f1e-7068-47ef-b013-ef19991db34d'	System	21 Aug 2020 23:06:37
User entered 'None (1)'	System	21 Aug 2020 23:06:37

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:06:19', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '04f25f1e-7068-47ef-b013-ef19991db34d'	System	21 Aug 2020 23:06:37
User entered 'No (N)'	System	21 Aug 2020 23:06:37

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:06:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '04f25f1e-7068-47ef-b013-ef19991db34d'	System	21 Aug 2020 23:06:37
User entered 'No (N)'	System	21 Aug 2020 23:06:37

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:06:24', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '04f25f1e-7068-47ef-b013-ef19991db34d'	System	21 Aug 2020 23:06:37
User entered 'None (1)'	System	21 Aug 2020 23:06:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:06:33', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '04f25f1e-7068-47ef-b013-ef19991db34d' User entered '21 Aug 2020 18:06'	System	21 Aug 2020 23:06:37
	System	21 Aug 2020 23:06:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 4'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:22:39', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54fed87e-d446-4725-94db-d3391b275243'	System	22 Aug 2020 23:23:26
User entered 'None (1)'	System	22 Aug 2020 23:23:26

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:22:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54fed87e-d446-4725-94db-d3391b275243'	System	22 Aug 2020 23:23:26
User entered 'No (N)'	System	22 Aug 2020 23:23:26

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:22:53', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54fed87e-d446-4725-94db-d3391b275243'	System	22 Aug 2020 23:23:26
User entered 'No (N)'	System	22 Aug 2020 23:23:26

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:07', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54fed87e-d446-4725-94db-d3391b275243'	System	22 Aug 2020 23:23:26
User entered 'None (1)'	System	22 Aug 2020 23:23:26

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:15', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54fed87e-d446-4725-94db-d3391b275243'	System	22 Aug 2020 23:23:26
User entered '22 Aug 2020 18:23'	System	22 Aug 2020 23:23:26

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 5'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:00:51', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '991088b5-1b59-4602-899f-c6d351b9db77'	System	24 Aug 2020 00:01:08
User entered 'None (1)'	System	24 Aug 2020 00:01:08

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:00:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '991088b5-1b59-4602-899f-c6d351b9db77'	System	24 Aug 2020 00:01:08
User entered 'No (N)'	System	24 Aug 2020 00:01:08

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:00:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '991088b5-1b59-4602-899f-c6d351b9db77'	System	24 Aug 2020 00:01:08
User entered 'No (N)'	System	24 Aug 2020 00:01:08

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '991088b5-1b59-4602-899f-c6d351b9db77'	System	24 Aug 2020 00:01:08
User entered 'None (1)'	System	24 Aug 2020 00:01:08

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '991088b5-1b59-4602-899f-c6d351b9db77'	System	24 Aug 2020 00:01:08
User entered '23 Aug 2020 19:01'	System	24 Aug 2020 00:01:08

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 6'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df29fcbc-eb25-4d62-af61-b106cba90c33'	System	24 Aug 2020 23:52:51
User entered 'None (1)'	System	24 Aug 2020 23:52:51

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:33', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df29fcbc-eb25-4d62-af61-b106cba90c33'	System	24 Aug 2020 23:52:51
User entered 'No (N)'	System	24 Aug 2020 23:52:51

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:35', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df29fcbc-eb25-4d62-af61-b106cba90c33'	System	24 Aug 2020 23:52:51
User entered 'No (N)'	System	24 Aug 2020 23:52:51

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df29fcbc-eb25-4d62-af61-b106cba90c33'	System	24 Aug 2020 23:52:51
User entered 'None (1)'	System	24 Aug 2020 23:52:51

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:46', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df29fcbc-eb25-4d62-af61-b106cba90c33'	System	24 Aug 2020 23:52:51
User entered '24 Aug 2020 18:52'	System	24 Aug 2020 23:52:51

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 7'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd685c22e-59b6-4466-971a-af09893bff29'	System	26 Aug 2020 00:39:59
User entered 'None (1)'	System	26 Aug 2020 00:39:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:41', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd685c22e-59b6-4466-971a-af09893bff29'	System	26 Aug 2020 00:39:59
User entered 'No (N)'	System	26 Aug 2020 00:39:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd685c22e-59b6-4466-971a-af09893bff29' User entered 'No (N)'	System	26 Aug 2020 00:39:59
	System	26 Aug 2020 00:39:59

US3212250

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:46', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd685c22e-59b6-4466-971a-af09893bff29'	System	26 Aug 2020 00:39:59
User entered 'None (1)'	System	26 Aug 2020 00:39:59

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:39:54', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd685c22e-59b6-4466-971a-af09893bff29' User entered '25 Aug 2020 19:39'	System	26 Aug 2020 00:39:59
	System	26 Aug 2020 00:39:59

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:33:29

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:12:35', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered 'None (0)'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:12:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered 'None (0)'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:12:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered 'None (0)'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:12:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered 'None (0)'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:13:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered 'None (0)'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:13:02', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered 'None (0)'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18



US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:13:08', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered 'No (N)'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T16:13:15', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '3baf5157-b83e-41b0-bcb5-e352705a8c5a' User entered '19 Aug 2020 16:13'	System	19 Aug 2020 21:13:18
	System	19 Aug 2020 21:13:18

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 15:52'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 18:22'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:04', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered 'None (0)'	System	20 Aug 2020 01:06:54

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered 'None (0)'	System	20 Aug 2020 01:06:54

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:13', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered 'None (0)'	System	20 Aug 2020 01:06:54



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered 'None (0)'	System	20 Aug 2020 01:06:54

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:19', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered 'None (0)'	System	20 Aug 2020 01:06:54

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered 'None (0)'	System	20 Aug 2020 01:06:54

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:28', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered 'No (N)'	System	20 Aug 2020 01:06:54

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-19T20:06:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'df40faeb-6d08-4be1-be3c-75799f1ad697'	System	20 Aug 2020 01:06:54
User entered '19 Aug 2020 20:06'	System	20 Aug 2020 01:06:54

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Aug 2020 19:17'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 2'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:42', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered 'None (0)'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered 'None (0)'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:17:52', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered 'None (0)'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:18:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered 'None (0)'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:18:08', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered 'None (0)'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:18:10', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered 'None (0)'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:18:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered 'No (N)'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-20T18:18:27', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2e11f32f-4399-40d4-aaba-05e7dad94521' User entered '20 Aug 2020 18:18'	System	20 Aug 2020 23:18:31
	System	20 Aug 2020 23:18:31



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 3'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:07:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered 'None (0)'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:07:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered 'None (0)'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:08:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered 'None (0)'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:08:03', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered 'None (0)'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:08:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered 'None (0)'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37



US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:08:08', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered 'None (0)'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:08:11', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered 'No (N)'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-21T18:08:35', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bdf5e2aa-38f4-4987-8195-9840bdf9d56d' User entered '21 Aug 2020 18:08'	System	21 Aug 2020 23:08:37
	System	21 Aug 2020 23:08:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 4'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:27', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25' User entered 'None (0)'	System	22 Aug 2020 23:24:04
	System	22 Aug 2020 23:24:04

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:32', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25'	System	22 Aug 2020 23:24:04
User entered 'None (0)'	System	22 Aug 2020 23:24:04



US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25' User entered 'None (0)'	System	22 Aug 2020 23:24:04
	System	22 Aug 2020 23:24:04

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:43', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25' User entered 'None (0)'	System	22 Aug 2020 23:24:04
	System	22 Aug 2020 23:24:04

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:47', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25' User entered 'None (0)'	System	22 Aug 2020 23:24:04
	System	22 Aug 2020 23:24:04

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25' User entered 'None (0)'	System	22 Aug 2020 23:24:04
	System	22 Aug 2020 23:24:04

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:23:54', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25'	System	22 Aug 2020 23:24:04
User entered 'No (N)'	System	22 Aug 2020 23:24:04

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-22T18:24:03', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '94df066f-e637-4ef8-9daa-b75bb9707d25'	System	22 Aug 2020 23:24:04
User entered '22 Aug 2020 18:24'	System	22 Aug 2020 23:24:04

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 5'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:19', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered 'None (0)'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:24', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered 'None (0)'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:26', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered 'None (0)'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered 'None (0)'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:32', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered 'None (0)'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:37', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered 'None (0)'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:45', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered 'No (N)'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-23T19:01:52', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '247cad16-92a6-44ea-a3d0-211d27964d76' User entered '23 Aug 2020 19:01'	System	24 Aug 2020 00:01:55
	System	24 Aug 2020 00:01:55

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 6'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:54', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered 'None (0)'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:52:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered 'None (0)'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:53:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered 'None (0)'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:53:03', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered 'None (0)'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:53:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered 'None (0)'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:53:08', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered 'None (0)'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:53:14', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered 'No (N)'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-24T18:53:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f33851f-8d5c-4a79-97c0-43848e2fcc9b' User entered '24 Aug 2020 18:53'	System	24 Aug 2020 23:53:24
	System	24 Aug 2020 23:53:24

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 7'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:03', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492'	System	26 Aug 2020 00:40:37
User entered 'None (0)'	System	26 Aug 2020 00:40:37



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492'	System	26 Aug 2020 00:40:37
User entered 'None (0)'	System	26 Aug 2020 00:40:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:07', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492' User entered 'None (0)'	System	26 Aug 2020 00:40:37
	System	26 Aug 2020 00:40:37

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492' User entered 'None (0)'	System	26 Aug 2020 00:40:37
	System	26 Aug 2020 00:40:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492' User entered 'None (0)'	System	26 Aug 2020 00:40:37
	System	26 Aug 2020 00:40:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492'	System	26 Aug 2020 00:40:37
User entered 'None (0)'	System	26 Aug 2020 00:40:37

US3212250

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:26', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492'	System	26 Aug 2020 00:40:37
User entered 'No (N)'	System	26 Aug 2020 00:40:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-08-25T19:40:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927c62fd-d0a2-4fbe-a1a1-cabbe76c6492'	System	26 Aug 2020 00:40:37
User entered '25 Aug 2020 19:40'	System	26 Aug 2020 00:40:37

**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 13:52:06

**US3212250**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '26 Aug 2020'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 13:52:06

**US3212250**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 13:52:06

**US3212250**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	27 Aug 2020 13:52:06

US3212250

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	27 Aug 2020 13:52:13

**US3212250**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	27 Aug 2020 13:52:13

**US3212250**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Sep 2020 14:08:42



**US3212250**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '02 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	10 Nov 2020 17:10:39
User entered '2 Sep 2020'	Laura Ngansop Djampou (b) (4)	03 Sep 2020 14:08:42

**US3212250**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	03 Sep 2020 14:08:42

US3212250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:49:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Sep 2020 14:08:42

US3212250

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Sep 2020 14:09:54

**US3212250**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	03 Sep 2020 14:09:54

**US3212250**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	10 Sep 2020 17:12:49

**US3212250**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '09 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	09 Dec 2020 21:18:56
User entered '9 Sep 2020'	Laura Ngansop Djampou (b) (4)	10 Sep 2020 17:12:49

**US3212250**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	10 Sep 2020 17:12:49



US3212250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:49:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	10 Sep 2020 17:12:49

**US3212250**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	10 Sep 2020 17:12:55

**US3212250**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	10 Sep 2020 17:12:55

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Sep 2020 18:32:42

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Sep 2020'	Afifah Ayub (b) (4)	16 Sep 2020 18:32:42

US3212250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:49:32

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 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	16 Sep 2020 18:32:42

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'VISIT2'	System	16 Sep 2020 18:32:42

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou	16 Sep 2020 19:17:07
	(b) (4)	



US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Sep 2020'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '12:05'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Sep 2020 12:05'	System	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '97.8' F	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '85'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07



**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'bpm'	System	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'breaths/min'	System	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '139'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '70'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:07

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	16 Sep 2020 19:17:07

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Post-Dose (POSTDOSE)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53



US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Sep 2020'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:59'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Sep 2020 13:59'	System	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '97.8' F	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '76'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53



**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'bpm'	System	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'breaths/min'	System	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '143'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '68'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 19:17:53

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	16 Sep 2020 19:17:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Sep 2020 18:32:53



US3212250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:49:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Sep 2020'	Afifah Ayub (b) (4)	16 Sep 2020 18:32:53

US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Sep 2020 18:33:28

US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	16 Sep 2020 18:33:28

US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

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)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	16 Sep 2020 18:33:28

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:49:32**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 18:33:28

US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Sep 2020'	Afifah Ayub (b) (4)	16 Sep 2020 18:33:28

US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:17'	Afifah Ayub (b) (4)	16 Sep 2020 18:33:28

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:49:32**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Sep 2020 13:17'	System	16 Sep 2020 18:33:28



US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Left Arm (LEFT ARM)'	Afifah Ayub (b) (4)	16 Sep 2020 18:33:28

US3212250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:49:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'ONCE'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:49:32**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 18:33:28

US3212250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:29

US3212250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 17:02:34
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		17 Sep 2020 17:02:34
User entered '16 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	17 Sep 2020 17:02:34
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 17:02:29
User entered '17 Sep 2020'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:29

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:14'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:29

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Sep 2020 13:14'	System	17 Sep 2020 17:02:34
User entered '17 Sep 2020 13:14'	System	17 Sep 2020 17:02:29

US3212250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:49:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Sep 2020'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:49



**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 17:02:49

US3212250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:49:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:49

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:49:32**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:10'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:49

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Sep 2020 13:10'	System	17 Sep 2020 17:02:49

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 17:02:49

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'No (N)'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:49

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:49:32**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:02:49

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered empty.	System	17 Sep 2020 17:02:49



US3212250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	17 Sep 2020 17:02:55

**US3212250**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'I'	System	17 Sep 2020 17:02:55

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:00:35', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '21fa3eca-f6ea-4d64-b311-b182556687af' User entered 'Yes (Y)'	System	16 Sep 2020 19:01:01
	System	16 Sep 2020 19:01:01

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:00:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '21fa3eca-f6ea-4d64-b311-b182556687af' User entered '97.8'	System	16 Sep 2020 19:01:01
	System	16 Sep 2020 19:01:01

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:00:49', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '21fa3eca-f6ea-4d64-b311-b182556687af' User entered 'No (N)'	System	16 Sep 2020 19:01:01
	System	16 Sep 2020 19:01:01

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:00:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '21fa3eca-f6ea-4d64-b311-b182556687af' User entered '16 Sep 2020 14:00'	System	16 Sep 2020 19:01:01
	System	16 Sep 2020 19:01:01

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 13:37'	System	16 Sep 2020 18:33:28



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 16:07'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:10:54', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bef559ee-f2e4-42db-800f-22365eddf96b' User entered 'Yes (Y)'	System	16 Sep 2020 23:11:37
	System	16 Sep 2020 23:11:37

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:11:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bef559ee-f2e4-42db-800f-22365eddf96b' User entered '98.8'	System	16 Sep 2020 23:11:37
	System	16 Sep 2020 23:11:37

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:11:21', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bef559ee-f2e4-42db-800f-22365eddf96b'	System	16 Sep 2020 23:11:37
User entered 'No (N)'	System	16 Sep 2020 23:11:37

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:11:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'bef559ee-f2e4-42db-800f-22365eddf96b'	System	16 Sep 2020 23:11:37
User entered '16 Sep 2020 18:11'	System	16 Sep 2020 23:11:37

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 17:02'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:33:28



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 2'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:47:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c149ca80-3039-410c-af4c-e48383b1c13e' User entered 'Yes (Y)'	System	17 Sep 2020 23:48:00
	System	17 Sep 2020 23:48:00

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:47:42', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c149ca80-3039-410c-af4c-e48383b1c13e' User entered '99.7'	System	17 Sep 2020 23:48:00
	System	17 Sep 2020 23:48:00

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:47:51', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c149ca80-3039-410c-af4c-e48383b1c13e' User entered 'No (N)'	System	17 Sep 2020 23:48:00
	System	17 Sep 2020 23:48:00

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:47:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'c149ca80-3039-410c-af4c-e48383b1c13e' User entered '17 Sep 2020 18:47'	System	17 Sep 2020 23:48:00
	System	17 Sep 2020 23:48:00

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 3'	System	16 Sep 2020 18:33:28



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:45:39', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '46cb697c-06f4-4aaf-a618-ef0ea65a856f' User entered 'Yes (Y)'	System	18 Sep 2020 22:45:58
	System	18 Sep 2020 22:45:58

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:45:46', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '46cb697c-06f4-4aaf-a618-ef0ea65a856f' User entered '97.5'	System	18 Sep 2020 22:45:58
	System	18 Sep 2020 22:45:58

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:45:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '46cb697c-06f4-4aaf-a618-ef0ea65a856f' User entered 'No (N)'	System	18 Sep 2020 22:45:58
	System	18 Sep 2020 22:45:58

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:45:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '46cb697c-06f4-4aaf-a618-ef0ea65a856f' User entered '18 Sep 2020 17:45'	System	18 Sep 2020 22:45:58
	System	18 Sep 2020 22:45:58

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 4'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:15', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '29335e53-afb6-4a46-80e7-1321e0f51a01' User entered 'Yes (Y)'	System	20 Sep 2020 02:53:36
	System	20 Sep 2020 02:53:36



US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:21', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '29335e53-afb6-4a46-80e7-1321e0f51a01' User entered '97.7'	System	20 Sep 2020 02:53:36
	System	20 Sep 2020 02:53:36

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:24', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '29335e53-afb6-4a46-80e7-1321e0f51a01' User entered 'No (N)'	System	20 Sep 2020 02:53:36
	System	20 Sep 2020 02:53:36

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '29335e53-afb6-4a46-80e7-1321e0f51a01' User entered '19 Sep 2020 21:53'	System	20 Sep 2020 02:53:36
	System	20 Sep 2020 02:53:36

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 5'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:06', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a218763d-56d0-4b03-94f6-bedf8d163276' User entered 'Yes (Y)'	System	21 Sep 2020 01:56:25
	System	21 Sep 2020 01:56:25

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:13', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a218763d-56d0-4b03-94f6-bedf8d163276' User entered '98.7'	System	21 Sep 2020 01:56:25
	System	21 Sep 2020 01:56:25



US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a218763d-56d0-4b03-94f6-bedf8d163276' User entered 'No (N)'	System	21 Sep 2020 01:56:25
	System	21 Sep 2020 01:56:25

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a218763d-56d0-4b03-94f6-bedf8d163276' User entered '20 Sep 2020 20:56'	System	21 Sep 2020 01:56:25
	System	21 Sep 2020 01:56:25

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 6'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:46:30', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927e842e-e897-4c91-a55c-8e042b96ab28' User entered 'Yes (Y)'	System	21 Sep 2020 22:46:53
	System	21 Sep 2020 22:46:53

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:46:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927e842e-e897-4c91-a55c-8e042b96ab28' User entered '99.8'	System	21 Sep 2020 22:46:53
	System	21 Sep 2020 22:46:53

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:46:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927e842e-e897-4c91-a55c-8e042b96ab28'	System	21 Sep 2020 22:46:53
User entered 'No (N)'	System	21 Sep 2020 22:46:53



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:46:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '927e842e-e897-4c91-a55c-8e042b96ab28' User entered '21 Sep 2020 17:46'	System	21 Sep 2020 22:46:53
	System	21 Sep 2020 22:46:53

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 7'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:36:30', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '22067eaa-5f31-4e99-af39-51eada53a0'	System	22 Sep 2020 21:36:59
User entered 'Yes (Y)'	System	22 Sep 2020 21:36:59

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:36:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '22067eaa-5f31-4e99-af39-51eaedaf53a0' User entered '98.6'	System	22 Sep 2020 21:36:59
	System	22 Sep 2020 21:36:59

US3212250

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:36:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '22067eaa-5f31-4e99-af39-51eada53a0'	System	22 Sep 2020 21:36:59
User entered 'No (N)'	System	22 Sep 2020 21:36:59

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:36:54', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '22067eaa-5f31-4e99-af39-51eaedaf53a0' User entered '22 Sep 2020 16:36'	System	22 Sep 2020 21:36:59
	System	22 Sep 2020 21:36:59



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:01:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1a5d3407-4837-4214-83ea-32dff85ffa1f'	System	16 Sep 2020 19:01:44
User entered 'None (1)'	System	16 Sep 2020 19:01:44

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:01:23', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1a5d3407-4837-4214-83ea-32dff85ffa1f' User entered 'No (N)'	System	16 Sep 2020 19:01:44
	System	16 Sep 2020 19:01:44

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:01:26', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1a5d3407-4837-4214-83ea-32dff85ffa1f' User entered 'No (N)'	System	16 Sep 2020 19:01:44
	System	16 Sep 2020 19:01:44

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:01:37', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1a5d3407-4837-4214-83ea-32dff85ffa1f'	System	16 Sep 2020 19:01:44
User entered 'None (1)'	System	16 Sep 2020 19:01:44

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:01:42', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1a5d3407-4837-4214-83ea-32dff85ffa1f' User entered '16 Sep 2020 14:01'	System	16 Sep 2020 19:01:44
	System	16 Sep 2020 19:01:44



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 13:37'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 16:07'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:11:43', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e53ad7-6c9b-453f-aa26-947a8daf492c' User entered 'None (1)'	System	16 Sep 2020 23:12:20
	System	16 Sep 2020 23:12:20

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:11:53', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e53ad7-6c9b-453f-aa26-947a8daf492c' User entered 'No (N)'	System	16 Sep 2020 23:12:20
	System	16 Sep 2020 23:12:20

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:02', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e53ad7-6c9b-453f-aa26-947a8daf492c' User entered 'No (N)'	System	16 Sep 2020 23:12:20
	System	16 Sep 2020 23:12:20

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:13', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e53ad7-6c9b-453f-aa26-947a8daf492c' User entered 'None (1)'	System	16 Sep 2020 23:12:20
	System	16 Sep 2020 23:12:20

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '90e53ad7-6c9b-453f-aa26-947a8daf492c' User entered '16 Sep 2020 18:12'	System	16 Sep 2020 23:12:20
	System	16 Sep 2020 23:12:20



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 17:02'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 2'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:48:27', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '83ca3f89-c9b7-40c4-8193-fb0f01ccc201'	System	17 Sep 2020 23:48:52
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 23:48:52

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:48:31', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '83ca3f89-c9b7-40c4-8193-fb0f01ccc201' User entered 'No (N)'	System	17 Sep 2020 23:48:52
	System	17 Sep 2020 23:48:52

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:48:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '83ca3f89-c9b7-40c4-8193-fb0f01ccc201' User entered 'No (N)'	System	17 Sep 2020 23:48:52
	System	17 Sep 2020 23:48:52

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:48:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '83ca3f89-c9b7-40c4-8193-fb0f01ccc201'	System	17 Sep 2020 23:48:52
User entered 'None (1)'	System	17 Sep 2020 23:48:52

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:48:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '83ca3f89-c9b7-40c4-8193-fb0f01ccc201' User entered '17 Sep 2020 18:48'	System	17 Sep 2020 23:48:52
	System	17 Sep 2020 23:48:52



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 3'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '50b5f07c-38b4-462f-98f1-730c4a9d2722'	System	18 Sep 2020 22:46:20
User entered 'None (1)'	System	18 Sep 2020 22:46:20

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:03', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '50b5f07c-38b4-462f-98f1-730c4a9d2722'	System	18 Sep 2020 22:46:20
User entered 'No (N)'	System	18 Sep 2020 22:46:20

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:06', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '50b5f07c-38b4-462f-98f1-730c4a9d2722'	System	18 Sep 2020 22:46:20
User entered 'No (N)'	System	18 Sep 2020 22:46:20

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '50b5f07c-38b4-462f-98f1-730c4a9d2722'	System	18 Sep 2020 22:46:20
User entered 'None (1)'	System	18 Sep 2020 22:46:20

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:15', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '50b5f07c-38b4-462f-98f1-730c4a9d2722'	System	18 Sep 2020 22:46:20
User entered '18 Sep 2020 17:46'	System	18 Sep 2020 22:46:20



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 4'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:52:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '9833192b-6d8c-43a2-8742-4c458574bc9d'	System	20 Sep 2020 02:53:09
User entered 'None (1)'	System	20 Sep 2020 02:53:09

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:52:49', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '9833192b-6d8c-43a2-8742-4c458574bc9d' User entered 'No (N)'	System	20 Sep 2020 02:53:09
	System	20 Sep 2020 02:53:09

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:52:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '9833192b-6d8c-43a2-8742-4c458574bc9d' User entered 'No (N)'	System	20 Sep 2020 02:53:09
	System	20 Sep 2020 02:53:09

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '9833192b-6d8c-43a2-8742-4c458574bc9d'	System	20 Sep 2020 02:53:09
User entered 'None (1)'	System	20 Sep 2020 02:53:09

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:06', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '9833192b-6d8c-43a2-8742-4c458574bc9d' User entered '19 Sep 2020 21:53'	System	20 Sep 2020 02:53:09
	System	20 Sep 2020 02:53:09



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 5'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2c6671eb-743f-4d46-bff1-439114032447'	System	21 Sep 2020 01:56:52
User entered 'None (1)'	System	21 Sep 2020 01:56:52

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:33', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2c6671eb-743f-4d46-bff1-439114032447'	System	21 Sep 2020 01:56:52
User entered 'No (N)'	System	21 Sep 2020 01:56:52

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:37', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2c6671eb-743f-4d46-bff1-439114032447'	System	21 Sep 2020 01:56:52
User entered 'No (N)'	System	21 Sep 2020 01:56:52

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2c6671eb-743f-4d46-bff1-439114032447'	System	21 Sep 2020 01:56:52
User entered 'None (1)'	System	21 Sep 2020 01:56:52

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:56:51', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2c6671eb-743f-4d46-bff1-439114032447'	System	21 Sep 2020 01:56:52
User entered '20 Sep 2020 20:56'	System	21 Sep 2020 01:56:52



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 6'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:02', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '16bc1b5a-3c1c-476e-8962-9e00dcb08e59'	System	21 Sep 2020 22:47:31
User entered 'None (1)'	System	21 Sep 2020 22:47:31

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '16bc1b5a-3c1c-476e-8962-9e00dcb08e59'	System	21 Sep 2020 22:47:31
User entered 'No (N)'	System	21 Sep 2020 22:47:31

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:08', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '16bc1b5a-3c1c-476e-8962-9e00dcb08e59' User entered 'No (N)'	System	21 Sep 2020 22:47:31
	System	21 Sep 2020 22:47:31

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '16bc1b5a-3c1c-476e-8962-9e00dcb08e59'	System	21 Sep 2020 22:47:31
User entered 'None (1)'	System	21 Sep 2020 22:47:31

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '16bc1b5a-3c1c-476e-8962-9e00dcb08e59' User entered '21 Sep 2020 17:47'	System	21 Sep 2020 22:47:31
	System	21 Sep 2020 22:47:31



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 7'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'e5b06cbb-2a98-452b-ba95-ed2601e50f3b' User entered 'None (1)'	System	22 Sep 2020 21:37:24
	System	22 Sep 2020 21:37:24

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:08', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'e5b06cbb-2a98-452b-ba95-ed2601e50f3b' User entered 'No (N)'	System	22 Sep 2020 21:37:24
	System	22 Sep 2020 21:37:24

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:11', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'e5b06cbb-2a98-452b-ba95-ed2601e50f3b' User entered 'No (N)'	System	22 Sep 2020 21:37:24
	System	22 Sep 2020 21:37:24

US3212250

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:49:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'e5b06cbb-2a98-452b-ba95-ed2601e50f3b' User entered 'None (1)'	System	22 Sep 2020 21:37:24
	System	22 Sep 2020 21:37:24

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:23', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'e5b06cbb-2a98-452b-ba95-ed2601e50f3b' User entered '22 Sep 2020 16:37'	System	22 Sep 2020 21:37:24
	System	22 Sep 2020 21:37:24



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:01:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e' User entered 'None (0)'	System	16 Sep 2020 19:02:38
	System	16 Sep 2020 19:02:38

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:01:53', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e' User entered 'None (0)'	System	16 Sep 2020 19:02:38
	System	16 Sep 2020 19:02:38

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:02:07', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e' User entered 'None (0)'	System	16 Sep 2020 19:02:38
	System	16 Sep 2020 19:02:38

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:02:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e' User entered 'None (0)'	System	16 Sep 2020 19:02:38
	System	16 Sep 2020 19:02:38

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:02:20', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e' User entered 'None (0)'	System	16 Sep 2020 19:02:38
	System	16 Sep 2020 19:02:38



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:02:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e' User entered 'None (0)'	System	16 Sep 2020 19:02:38
	System	16 Sep 2020 19:02:38

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:02:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e'	System	16 Sep 2020 19:02:38
User entered 'No (N)'	System	16 Sep 2020 19:02:38

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T14:02:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '2fef89b7-c430-48d2-a7d1-877eeea1649e' User entered '16 Sep 2020 14:02'	System	16 Sep 2020 19:02:38
	System	16 Sep 2020 19:02:38

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 13:37'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 16:07'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered 'None (0)'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered 'None (0)'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40



US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered 'None (0)'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:51', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered 'None (0)'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:54', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered 'None (0)'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:12:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered 'None (0)'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:13:26', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered 'No (N)'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-16T18:13:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'f4318873-ed8d-4478-9c37-8b1abbafd66c' User entered '16 Sep 2020 18:13'	System	16 Sep 2020 23:13:40
	System	16 Sep 2020 23:13:40

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '16 Sep 2020 17:02'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 18:33:28



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 2'	System	16 Sep 2020 18:33:28

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff' User entered 'None (0)'	System	17 Sep 2020 23:49:47
	System	17 Sep 2020 23:49:47

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:13', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff'	System	17 Sep 2020 23:49:47
User entered 'No interference with activity (1)'	System	17 Sep 2020 23:49:47

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:18', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff' User entered 'None (0)'	System	17 Sep 2020 23:49:47
	System	17 Sep 2020 23:49:47

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:25', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff' User entered 'None (0)'	System	17 Sep 2020 23:49:47
	System	17 Sep 2020 23:49:47

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:28', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff' User entered 'None (0)'	System	17 Sep 2020 23:49:47
	System	17 Sep 2020 23:49:47

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:31', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff' User entered 'None (0)'	System	17 Sep 2020 23:49:47
	System	17 Sep 2020 23:49:47

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff'	System	17 Sep 2020 23:49:47
User entered 'No (N)'	System	17 Sep 2020 23:49:47



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-17T18:49:45', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4a3d714a-c8c3-4d3b-83bc-a9a22f8caaff' User entered '17 Sep 2020 18:49'	System	17 Sep 2020 23:49:47
	System	17 Sep 2020 23:49:47

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 3'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:20', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa' User entered 'None (0)'	System	18 Sep 2020 22:46:49
	System	18 Sep 2020 22:46:49

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:25', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa' User entered 'None (0)'	System	18 Sep 2020 22:46:49
	System	18 Sep 2020 22:46:49

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa' User entered 'None (0)'	System	18 Sep 2020 22:46:49
	System	18 Sep 2020 22:46:49

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:31', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa' User entered 'None (0)'	System	18 Sep 2020 22:46:49
	System	18 Sep 2020 22:46:49



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa' User entered 'None (0)'	System	18 Sep 2020 22:46:49
	System	18 Sep 2020 22:46:49

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa' User entered 'None (0)'	System	18 Sep 2020 22:46:49
	System	18 Sep 2020 22:46:49

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa'	System	18 Sep 2020 22:46:49
User entered 'No (N)'	System	18 Sep 2020 22:46:49

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-18T17:46:47', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '1b0589eb-dffb-4210-9e96-de6cb5b13aaa' User entered '18 Sep 2020 17:46'	System	18 Sep 2020 22:46:49
	System	18 Sep 2020 22:46:49

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 4'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered 'None (0)'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered 'None (0)'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered 'None (0)'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered 'None (0)'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:43', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered 'None (0)'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:45', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered 'None (0)'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:53:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered 'No (N)'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-19T21:54:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'af660ef1-37f5-4ab9-b1de-dcf7d9d2eb18' User entered '19 Sep 2020 21:54'	System	20 Sep 2020 02:54:02
	System	20 Sep 2020 02:54:02

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 18:33:28



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 5'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered 'None (0)'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:02', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered 'None (0)'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:04', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered 'None (0)'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:06', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered 'None (0)'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered 'None (0)'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:11', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered 'None (0)'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24



US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered 'No (N)'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-20T20:57:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'beacf388-cc91-407d-828e-dffbe01b73a7' User entered '20 Sep 2020 20:57'	System	21 Sep 2020 01:57:24
	System	21 Sep 2020 01:57:24

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 6'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:35', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered 'None (0)'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered 'None (0)'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered 'None (0)'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03



US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:42', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered 'None (0)'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered 'None (0)'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:47', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered 'None (0)'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:47:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered 'No (N)'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-21T17:48:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '984125cc-75e8-4305-923f-5c3a296b51cf' User entered '21 Sep 2020 17:48'	System	21 Sep 2020 22:48:03
	System	21 Sep 2020 22:48:03

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	16 Sep 2020 18:33:28
User entered 'Day 7'	System	16 Sep 2020 18:33:28



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44' User entered 'None (0)'	System	22 Sep 2020 21:37:53
	System	22 Sep 2020 21:37:53

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:31', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44' User entered 'None (0)'	System	22 Sep 2020 21:37:53
	System	22 Sep 2020 21:37:53

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:34', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44' User entered 'None (0)'	System	22 Sep 2020 21:37:53
	System	22 Sep 2020 21:37:53

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44' User entered 'None (0)'	System	22 Sep 2020 21:37:53
	System	22 Sep 2020 21:37:53

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44' User entered 'None (0)'	System	22 Sep 2020 21:37:53
	System	22 Sep 2020 21:37:53

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:41', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44' User entered 'None (0)'	System	22 Sep 2020 21:37:53
	System	22 Sep 2020 21:37:53

US3212250

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:49:32

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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:45', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44'	System	22 Sep 2020 21:37:53
User entered 'No (N)'	System	22 Sep 2020 21:37:53

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-09-22T16:37:52', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ee4e0ca6-3bd1-442e-81cd-0ba276b5df44' User entered '22 Sep 2020 16:37'	System	22 Sep 2020 21:37:53
	System	22 Sep 2020 21:37:53



**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:49:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 18:33:28

**US3212250**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 13:29:35

**US3212250**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '23 Sep 2020'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 13:29:35

**US3212250**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 13:29:35

**US3212250**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	24 Sep 2020 13:29:35

US3212250

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	24 Sep 2020 13:29:41

**US3212250**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	24 Sep 2020 13:29:41



**US3212250**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 16:11:26

US3212250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:49:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Oct 2020 16:13:29
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	01 Oct 2020 16:13:29
User entered '30 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	01 Oct 2020 16:13:29
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Oct 2020 16:11:26
User entered '23 Sep 2020'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 16:11:26

**US3212250**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 16:11:26

US3212250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:49:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Oct 2020 16:11:26

US3212250

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 16:13:13

**US3212250**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	01 Oct 2020 16:13:13

**US3212250**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:35:23

**US3212250**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '07 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	09 Dec 2020 21:19:17
User entered '7 Oct 2020'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:35:23



**US3212250**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:35:23

**US3212250**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:35:23

US3212250

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:35:28

**US3212250**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	08 Oct 2020 14:35:28

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:28:40

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:28:40

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[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 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:28:40

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'VISIT3'	System	16 Oct 2020 21:28:40



US3212250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '12:13'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Oct 2020 12:13'	System	16 Oct 2020 21:29:25

US3212250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '97.1' F	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '89'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25



**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'bpm'	System	16 Oct 2020 21:29:25

US3212250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '14'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

US3212250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'breaths/min'	System	16 Oct 2020 21:29:25

US3212250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '134'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	16 Oct 2020 21:29:25

US3212250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '78'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	16 Oct 2020 21:29:25

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43



**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43

US3212250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:28:52

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:49:32**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:28:52

US3212250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:38

US3212250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:38

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:06'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:29:38

**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Oct 2020 13:06'	System	16 Oct 2020 21:29:38

US3212250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:28:56



**US3212250**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'I'	System	16 Oct 2020 21:28:56

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 64'	System	19 Aug 2020 20:33:29

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

[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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-10-22T15:49:18', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '6ce2f664-148d-4082-98f3-2e1b084bef56'	System	22 Oct 2020 20:49:40
User entered 'No (N)'	System	22 Oct 2020 20:49:40

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

Have you been exposed to someone with 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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-10-22T15:49:24', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '6ce2f664-148d-4082-98f3-2e1b084bef56'	System	22 Oct 2020 20:49:40
User entered 'No (N)'	System	22 Oct 2020 20:49:40

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-10-22T15:49:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '6ce2f664-148d-4082-98f3-2e1b084bef56' User entered '22 Oct 2020 15:49:36'	System	22 Oct 2020 20:49:40
	System	22 Oct 2020 20:49:40

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 71'	System	19 Aug 2020 20:33:29



US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

[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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-10-26T16:30:41', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '861d7a0f-0ef2-473f-8b51-12acac479940'	System	26 Oct 2020 21:30:55
User entered 'No (N)'	System	26 Oct 2020 21:30:55

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

Have you been exposed to someone with 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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-10-26T16:30:47', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '861d7a0f-0ef2-473f-8b51-12acac479940'	System	26 Oct 2020 21:30:55
User entered 'No (N)'	System	26 Oct 2020 21:30:55

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-10-26T16:30:52', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '861d7a0f-0ef2-473f-8b51-12acac479940' User entered '26 Oct 2020 16:30:52'	System	26 Oct 2020 21:30:55
	System	26 Oct 2020 21:30:55

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 78'	System	19 Aug 2020 20:33:29

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

[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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-02T09:36:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '34b3f3b0-462d-4727-b347-5b88a0c202e9' User entered 'No (N)'	System	02 Nov 2020 15:37:06
	System	02 Nov 2020 15:37:06

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

Have you been exposed to someone with 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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-02T09:36:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '34b3f3b0-462d-4727-b347-5b88a0c202e9' User entered 'No (N)'	System	02 Nov 2020 15:37:06
	System	02 Nov 2020 15:37:06



**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-02T09:37:03', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '34b3f3b0-462d-4727-b347-5b88a0c202e9' User entered '02 Nov 2020 09:37:03'	System	02 Nov 2020 15:37:06
	System	02 Nov 2020 15:37:06

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered 'Day 92'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-16T15:03:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f7d0d0b-ed6d-4e97-bcaf-0dc3ab2f3bca' User entered 'No (N)'	System	16 Nov 2020 21:03:20
	System	16 Nov 2020 21:03:20

US3212250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:49:32

Have you been exposed to someone with 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)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-16T15:03:06', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f7d0d0b-ed6d-4e97-bcaf-0dc3ab2f3bca' User entered 'No (N)'	System	16 Nov 2020 21:03:20
	System	16 Nov 2020 21:03:20

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-16T15:03:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '4f7d0d0b-ed6d-4e97-bcaf-0dc3ab2f3bca' User entered '16 Nov 2020 15:03:17'	System	16 Nov 2020 21:03:20
	System	16 Nov 2020 21:03:20

**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:33:29



**US3212250**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:08:09
Data entry locked.	System	19 Aug 2020 20:33:29
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:33:29

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-23T11:29:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8f50f2a-609a-42f1-9b3e-c01c1cf5ff9'	System	23 Nov 2020 17:30:05
User entered 'No (N)'	System	23 Nov 2020 17:30:05

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-23T11:29:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8f50f2a-609a-42f1-9b3e-c01c1cfd5ff9'	System	23 Nov 2020 17:30:05
User entered 'No (N)'	System	23 Nov 2020 17:30:05

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-23T11:29:59', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a8f50f2a-609a-42f1-9b3e-c01c1cfd5ff9'	System	23 Nov 2020 17:30:05
User entered '23 Nov 2020 11:29:59'	System	23 Nov 2020 17:30:05

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-30T09:47:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ec55830f-8fa6-4ff5-9963-88c001ca2507'	System	30 Nov 2020 15:47:34
User entered 'No (N)'	System	30 Nov 2020 15:47:34

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-30T09:47:20', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ec55830f-8fa6-4ff5-9963-88c001ca2507'	System	30 Nov 2020 15:47:34
User entered 'No (N)'	System	30 Nov 2020 15:47:34

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-11-30T09:47:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'ec55830f-8fa6-4ff5-9963-88c001ca2507' User entered '30 Nov 2020 09:47:29'	System	30 Nov 2020 15:47:34

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-07T11:00:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd76d6b3e-1adb-4f50-8c41-2b2103ef547e' User entered 'No (N)'	System	07 Dec 2020 17:01:29
	System	07 Dec 2020 17:01:29

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-07T11:00:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd76d6b3e-1adb-4f50-8c41-2b2103ef547e' User entered 'No (N)'	System	07 Dec 2020 17:01:29
	System	07 Dec 2020 17:01:29



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-07T11:01:11', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd76d6b3e-1adb-4f50-8c41-2b2103ef547e' User entered '07 Dec 2020 11:01:11'	System	07 Dec 2020 17:01:29
	System	07 Dec 2020 17:01:29

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-14T09:27:52', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '073f6775-fe09-40ae-9511-7c6755434020' User entered 'No (N)'	System	14 Dec 2020 15:28:12
	System	14 Dec 2020 15:28:12

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-14T09:28:00', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '073f6775-fe09-40ae-9511-7c6755434020' User entered 'No (N)'	System	14 Dec 2020 15:28:12
	System	14 Dec 2020 15:28:12

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-14T09:28:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '073f6775-fe09-40ae-9511-7c6755434020' User entered '14 Dec 2020 09:28:09'	System	14 Dec 2020 15:28:12
	System	14 Dec 2020 15:28:12

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-21T07:10:06', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '35e69e1e-ddeb-4e67-94a5-87fbab0c672e' User entered 'No (N)'	System	21 Dec 2020 13:10:21
	System	21 Dec 2020 13:10:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-21T07:10:12', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '35e69e1e-ddeb-4e67-94a5-87fbab0c672e' User entered 'No (N)'	System	21 Dec 2020 13:10:21
	System	21 Dec 2020 13:10:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-21T07:10:18', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '35e69e1e-ddeb-4e67-94a5-87fbab0c672e' User entered '21 Dec 2020 07:10:18'	System	21 Dec 2020 13:10:21
	System	21 Dec 2020 13:10:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-28T09:21:45', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '028c6bd3-4bf0-4bb7-ad00-fecae7ad8894' User entered 'No (N)'	System	28 Dec 2020 15:22:03
	System	28 Dec 2020 15:22:03

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-28T09:21:51', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '028c6bd3-4bf0-4bb7-ad00-fecae7ad8894' User entered 'No (N)'	System	28 Dec 2020 15:22:03
	System	28 Dec 2020 15:22:03

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2020-12-28T09:22:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '028c6bd3-4bf0-4bb7-ad00-fecae7ad8894' User entered '28 Dec 2020 09:22:01'	System	28 Dec 2020 15:22:03
	System	28 Dec 2020 15:22:03

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-04T09:46:45', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '0bcda473-f02c-4324-9666-4b4565f3d353'	System	04 Jan 2021 15:47:35
User entered 'No (N)'	System	04 Jan 2021 15:47:35

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-04T09:46:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '0bcda473-f02c-4324-9666-4b4565f3d353'	System	04 Jan 2021 15:47:35
User entered 'Yes (Y)'	System	04 Jan 2021 15:47:35



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Please 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-04T09:47:14', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '0bcda473-f02c-4324-9666-4b4565f3d353'	System	04 Jan 2021 15:47:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 15:47:35

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-04T09:47:25', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '0bcda473-f02c-4324-9666-4b4565f3d353'	System	04 Jan 2021 15:47:35
User entered '04 Jan 2021 09:47:25'	System	04 Jan 2021 15:47:35

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-11T09:40:22', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'b72df8d5-46d0-4587-9000-5006d1df784a'	System	11 Jan 2021 15:40:43
User entered 'No (N)'	System	11 Jan 2021 15:40:43

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-11T09:40:31', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'b72df8d5-46d0-4587-9000-5006d1df784a'	System	11 Jan 2021 15:40:43
User entered 'No (N)'	System	11 Jan 2021 15:40:43

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-11T09:40:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'b72df8d5-46d0-4587-9000-5006d1df784a' User entered '11 Jan 2021 09:40:40'	System	11 Jan 2021 15:40:43
	System	11 Jan 2021 15:40:43



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-18T09:22:18', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd6f2c3f9-6d5e-4023-a068-7f2aaee92ab2'	System	18 Jan 2021 15:22:31
User entered 'No (N)'	System	18 Jan 2021 15:22:31

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-18T09:22:21', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd6f2c3f9-6d5e-4023-a068-7f2aaee92ab2'	System	18 Jan 2021 15:22:31
User entered 'No (N)'	System	18 Jan 2021 15:22:31

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-18T09:22:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd6f2c3f9-6d5e-4023-a068-7f2aaee92ab2'	System	18 Jan 2021 15:22:31
User entered '18 Jan 2021 09:22:29'	System	18 Jan 2021 15:22:31

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-25T08:36:48', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '034263ca-fc6a-47ec-88dd-522df1867de9' User entered 'No (N)'	System	25 Jan 2021 14:37:00
	System	25 Jan 2021 14:37:00

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-25T08:36:52', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '034263ca-fc6a-47ec-88dd-522df1867de9' User entered 'No (N)'	System	25 Jan 2021 14:37:00
	System	25 Jan 2021 14:37:00

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-01-25T08:36:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '034263ca-fc6a-47ec-88dd-522df1867de9' User entered '25 Jan 2021 08:36:57'	System	25 Jan 2021 14:37:00
	System	25 Jan 2021 14:37:00

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-01T07:45:13', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'dd340691-d7a1-40d6-885b-ddb409dac0f0'	System	01 Feb 2021 13:45:28
User entered 'No (N)'	System	01 Feb 2021 13:45:28



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-01T07:45:20', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'dd340691-d7a1-40d6-885b-ddb409dac0f0'	System	01 Feb 2021 13:45:28
User entered 'No (N)'	System	01 Feb 2021 13:45:28

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-01T07:45:26', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'dd340691-d7a1-40d6-885b-ddb409dac0f0'	System	01 Feb 2021 13:45:28
User entered '01 Feb 2021 07:45:26'	System	01 Feb 2021 13:45:28

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-08T09:53:26', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a6883eab-15bb-4d19-9a9d-76c4b6c3b63b' User entered 'Yes (Y)'	System	08 Feb 2021 15:54:25
	System	08 Feb 2021 15:54:25

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-08T09:53:35', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a6883eab-15bb-4d19-9a9d-76c4b6c3b63b' User entered 'No (N)'	System	08 Feb 2021 15:54:25
	System	08 Feb 2021 15:54:25

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-08T09:53:46', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a6883eab-15bb-4d19-9a9d-76c4b6c3b63b' User entered 'No (N)'	System	08 Feb 2021 15:54:25
	System	08 Feb 2021 15:54:25



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-08T09:53:55', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a6883eab-15bb-4d19-9a9d-76c4b6c3b63b' User entered 'Yes (Y)'	System	08 Feb 2021 15:54:25
	System	08 Feb 2021 15:54:25

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Please 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-08T09:54:05', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a6883eab-15bb-4d19-9a9d-76c4b6c3b63b'	System	08 Feb 2021 15:54:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Feb 2021 15:54:25

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-08T09:54:16', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'a6883eab-15bb-4d19-9a9d-76c4b6c3b63b' User entered '08 Feb 2021 09:54:16'	System	08 Feb 2021 15:54:25
	System	08 Feb 2021 15:54:25

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-15T06:56:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'fe70753f-579b-4046-9064-fe27aee8076e' User entered 'No (N)'	System	15 Feb 2021 12:57:32
	System	15 Feb 2021 12:57:32

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-15T06:55:51', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'fe70753f-579b-4046-9064-fe27aee8076e' User entered 'No (N)'	System	15 Feb 2021 12:57:32
	System	15 Feb 2021 12:57:32



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-15T06:57:27', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'fe70753f-579b-4046-9064-fe27aee8076e' User entered '15 Feb 2021 06:57:27'	System	15 Feb 2021 12:57:32
	System	15 Feb 2021 12:57:32

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-22T10:40:10', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '0147cffc-7f4d-4a5d-ad64-804a188fd442'	System	22 Feb 2021 16:40:21
User entered 'No (N)'	System	22 Feb 2021 16:40:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-22T10:40:14', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '0147cffc-7f4d-4a5d-ad64-804a188fd442'	System	22 Feb 2021 16:40:21
User entered 'No (N)'	System	22 Feb 2021 16:40:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-02-22T10:40:19', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '0147cffc-7f4d-4a5d-ad64-804a188fd442'	System	22 Feb 2021 16:40:21
User entered '22 Feb 2021 10:40:19'	System	22 Feb 2021 16:40:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-01T07:15:46', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '7c287818-8196-4aa3-a327-ea634af5e55e'	System	01 Mar 2021 13:16:00
User entered 'No (N)'	System	01 Mar 2021 13:16:00

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-01T07:15:51', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '7c287818-8196-4aa3-a327-ea634af5e55e'	System	01 Mar 2021 13:16:00
User entered 'No (N)'	System	01 Mar 2021 13:16:00

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-01T07:15:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '7c287818-8196-4aa3-a327-ea634af5e55e'	System	01 Mar 2021 13:16:00
User entered '01 Mar 2021 07:15:57'	System	01 Mar 2021 13:16:00

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-08T10:17:21', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '5aa5759e-5459-4712-afa1-df3b6f8a594d'	System	08 Mar 2021 16:17:32
User entered 'No (N)'	System	08 Mar 2021 16:17:32

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-08T10:17:24', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '5aa5759e-5459-4712-afa1-df3b6f8a594d' User entered 'No (N)'	System	08 Mar 2021 16:17:32

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-08T10:17:29', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '5aa5759e-5459-4712-afa1-df3b6f8a594d' User entered '08 Mar 2021 10:17:29'	System	08 Mar 2021 16:17:32
	System	08 Mar 2021 16:17:32

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-15T09:34:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '56192553-4e27-44ac-84b2-d85111bb872d' User entered 'No (N)'	System	15 Mar 2021 14:34:21
	System	15 Mar 2021 14:34:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-15T09:34:13', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '56192553-4e27-44ac-84b2-d85111bb872d'	System	15 Mar 2021 14:34:21
User entered 'No (N)'	System	15 Mar 2021 14:34:21



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-15T09:34:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '56192553-4e27-44ac-84b2-d85111bb872d' User entered '15 Mar 2021 09:34:17'	System	15 Mar 2021 14:34:21
	System	15 Mar 2021 14:34:21

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-22T05:55:12', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd7ab0981-f537-4edc-9cdf-b754d4c9a802'	System	22 Mar 2021 10:55:28
User entered 'No (N)'	System	22 Mar 2021 10:55:28

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-22T05:55:15', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd7ab0981-f537-4edc-9cdf-b754d4c9a802'	System	22 Mar 2021 10:55:28
User entered 'No (N)'	System	22 Mar 2021 10:55:28

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-22T05:55:26', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'd7ab0981-f537-4edc-9cdf-b754d4c9a802'	System	22 Mar 2021 10:55:28
User entered '22 Mar 2021 05:55:26'	System	22 Mar 2021 10:55:28

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-29T14:26:38', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'b3c70f4e-5162-4b1e-85df-84974f6fdfe0'	System	29 Mar 2021 19:26:50
User entered 'No (N)'	System	29 Mar 2021 19:26:50

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-29T14:26:40', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'b3c70f4e-5162-4b1e-85df-84974f6fdfe0'	System	29 Mar 2021 19:26:50
User entered 'No (N)'	System	29 Mar 2021 19:26:50

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-29T14:26:44', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'b3c70f4e-5162-4b1e-85df-84974f6fdfe0' User entered '29 Mar 2021 14:26:44'	System	29 Mar 2021 19:26:50
	System	29 Mar 2021 19:26:50

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-05T07:52:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8feee83e-f120-4981-9e51-bf2ba413fa52'	System	05 Apr 2021 12:53:03
User entered 'No (N)'	System	05 Apr 2021 12:53:03

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-05T07:52:52', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8feee83e-f120-4981-9e51-bf2ba413fa52'	System	05 Apr 2021 12:53:03
User entered 'No (N)'	System	05 Apr 2021 12:53:03

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-05T07:53:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '8feee83e-f120-4981-9e51-bf2ba413fa52'	System	05 Apr 2021 12:53:03
User entered '05 Apr 2021 07:53:01'	System	05 Apr 2021 12:53:03

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-12T06:12:58', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '48e3aa58-009c-4280-aea9-2a00bb62aeae' User entered 'No (N)'	System	12 Apr 2021 11:13:11
	System	12 Apr 2021 11:13:11

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-12T06:13:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '48e3aa58-009c-4280-aea9-2a00bb62aeae' User entered 'No (N)'	System	12 Apr 2021 11:13:11



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-12T06:13:08', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '48e3aa58-009c-4280-aea9-2a00bb62aeae' User entered '12 Apr 2021 06:13:08'	System	12 Apr 2021 11:13:11
	System	12 Apr 2021 11:13:11

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-19T23:35:57', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '37ff4c02-42ab-4d42-8f86-089588de6b1e' User entered 'No (N)'	System	20 Apr 2021 04:36:16
	System	20 Apr 2021 04:36:16

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-19T23:36:01', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '37ff4c02-42ab-4d42-8f86-089588de6b1e' User entered 'No (N)'	System	20 Apr 2021 04:36:16
	System	20 Apr 2021 04:36:16

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-19T23:36:09', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '37ff4c02-42ab-4d42-8f86-089588de6b1e' User entered '19 Apr 2021 23:36:09'	System	20 Apr 2021 04:36:16
	System	20 Apr 2021 04:36:16

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-26T11:48:15', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'fefb12f8-26fb-4fa7-8c2d-b359e68d8879' User entered 'No (N)'	System	26 Apr 2021 16:48:26
	System	26 Apr 2021 16:48:26

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-26T11:48:17', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'fefb12f8-26fb-4fa7-8c2d-b359e68d8879' User entered 'No (N)'	System	26 Apr 2021 16:48:26

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-04-26T11:48:24', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: 'fefb12f8-26fb-4fa7-8c2d-b359e68d8879' User entered '26 Apr 2021 11:48:24'	System	26 Apr 2021 16:48:26
	System	26 Apr 2021 16:48:26

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-05-03T07:51:27', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54244ddd-525f-495b-9248-4e00b6b2a7ed'	System	03 May 2021 12:51:40
User entered 'No (N)'	System	03 May 2021 12:51:40

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

Have you been exposed to someone with 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 (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-05-03T07:51:30', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54244ddd-525f-495b-9248-4e00b6b2a7ed'	System	03 May 2021 12:51:40
User entered 'No (N)'	System	03 May 2021 12:51:40

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-05-03T07:51:36', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '54244ddd-525f-495b-9248-4e00b6b2a7ed'	System	03 May 2021 12:51:40
User entered '03 May 2021 07:51:36'	System	03 May 2021 12:51:40

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:17:15



**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:17:15

**US3212250**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:49:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:15
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:17:15

US3212250

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:49:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-08T10:17:37', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '25fd0c83-0fef-43f7-a4a6-48c6e369ae6f' User entered 'No (N)'	System	08 Mar 2021 16:17:53
	System	08 Mar 2021 16:17:53

**US3212250**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:33:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B0C761B2-766E-4301-BCD7-E1B34A6D42ED)', Time: '2021-03-08T10:17:50', User OID: 'PatientReportedOutcome (US3212250)', ODM File OID: '25fd0c83-0fef-43f7-a4a6-48c6e369ae6f' User entered '08 Mar 2021 10:17:50'	System	08 Mar 2021 16:17:53
	System	08 Mar 2021 16:17:53

**US3212250**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Nov 2020 15:39:52

**US3212250**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '11 Nov 2020'	Laura Ngansop Djampou (b) (4)	12 Nov 2020 15:39:52



**US3212250**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	12 Nov 2020 15:39:52

US3212250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:49:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	12 Nov 2020 15:39:52

US3212250

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	12 Nov 2020 15:39:58

**US3212250**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	12 Nov 2020 15:39:58

**US3212250**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Dec 2020 15:06:08

**US3212250**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '18 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Dec 2020 16:21:14
User entered '16 Dec 2020'	Laura Ngansop Djampou (b) (4)	17 Dec 2020 15:06:08

**US3212250**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Dec 2020 16:21:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laura Ngansop Djampou (b) (4)	17 Dec 2020 15:06:08

**US3212250**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	22 Dec 2020 16:21:14
User entered 'called for day 119, no answer, left a voicemail'	Laura Ngansop Djampou (b) (4)	17 Dec 2020 15:06:08



US3212250

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Dec 2020 15:06:12

**US3212250**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	17 Dec 2020 15:06:12

**US3212250**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	15 Jan 2021 18:19:35

**US3212250**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '14 Jan 2021'	Laura Ngansop Djampou (b) (4)	15 Jan 2021 18:19:35

**US3212250**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	15 Jan 2021 18:19:35

US3212250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:49:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Laura Ngansop Djampou (b) (4)	15 Jan 2021 18:19:35

US3212250

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	15 Jan 2021 18:20:02

**US3212250**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	15 Jan 2021 18:20:02



**US3212250**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	21 Feb 2021 20:22:12

**US3212250**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '12 Feb 2021'	Afifah Ayub (b) (4)	21 Feb 2021 20:22:12

**US3212250**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Contact Made (CONTACT MADE)'	Afifah Ayub (b) (4)	21 Feb 2021 20:22:12

**US3212250**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	21 Feb 2021 20:22:12

US3212250

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	21 Feb 2021 20:21:55

**US3212250**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:40
User entered 'I'	System	21 Feb 2021 20:21:55

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:16:58

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Mar 2021'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:16:58



US3212250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:49:32

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 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:16:58

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'VISIT4'	System	17 Mar 2021 14:16:58

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 17:23:03

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '11:53'	(b) (4), (b) (6)	30 Mar 2021 17:23:03

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Mar 2021 11:53'	System	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '97.7' F	(b) (4), (b) (6)	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 17:23:03



US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '70'	(b) (4), (b) (6)	30 Mar 2021 17:23:03

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'bpm'	System	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '17'	(b) (4), (b) (6)	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'breaths/min'	System	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '142'	(b) (4), (b) (6)	30 Mar 2021 17:23:03

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	30 Mar 2021 17:23:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:49:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '86'	(b) (4), (b) (6)	30 Mar 2021 17:23:03



**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'mmHg'	System	30 Mar 2021 17:23:03

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43

US3212250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:49:32

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:17:03

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:49:32**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Mar 2021'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:17:03

US3212250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:17:17

US3212250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:49:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '16 Mar 2021'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:17:17

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '12:33'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:17:17



**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered '16 Mar 2021 12:33'	System	17 Mar 2021 14:17:17

US3212250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:49:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:17:26

**US3212250**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:13:43
User entered 'I'	System	17 Mar 2021 14:17:26

**US3212250**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Apr 2021 16:19:41

fb

**US3212250**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '13 Apr 2021'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Apr 2021 16:19:41

**US3212250**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Apr 2021 16:19:41

**US3212250**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:49:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Apr 2021 16:19:41

**US3212250**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	(b) (4) Laura Ngansop Djampou (b) (4)	14 Apr 2021 16:19:31



**US3212250**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 16:19:31

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:05

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '19 Jan 2021'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:05

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:05

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:49:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 19:01:05

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '19 Jan 2021'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:17

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:32:21
User entered '0'	(b) (4) Heather Leary (b) (4)	22 Apr 2021 15:38:30
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:51:54

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:17



US3212250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:49:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 19:39:03
User signature succeeded.	Insiya Valika (b) (4)	22 Apr 2021 19:32:21
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'done' (Site from DM).	Heather Leary (b) (4)	22 Apr 2021 15:38:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	Heather Leary (b) (4)	22 Apr 2021 15:38:30
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 08:40:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:51:54

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '19 Jan 2021'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:17

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:17

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:46:16
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:17

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:46:16
User entered 'mRNA-1273 (mRNA-1273)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:17

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:17

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User entered empty.	System	19 Jan 2021 19:01:17

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:49:32**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User entered empty.	System	19 Jan 2021 19:01:17



**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:05:27

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '19 Jan 2021'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:05:27

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '11:59'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:05:27

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User entered '19 Jan 2021 11:59'	System	19 Jan 2021 19:05:27

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:49:32**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:42

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:49:32**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '19 Jan 2021'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:42

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:49:32**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '11:22'	Laura Ngansop Djampou (b) (4)	19 Jan 2021 19:01:42

**US3212250**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:49:32**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:52:45
User entered '19 Jan 2021 11:22'	System	19 Jan 2021 19:01:42



**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:44
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13 Nov 2020'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:12

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:44
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:12

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:44
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'I'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:12

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:44
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:12

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 15:49:32**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:44
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '0'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:12

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13 Nov 2020'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '13:55'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42



**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User entered '13 Nov 2020 13:55'	System	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '97.3' F	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered empty.	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '82'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User entered 'bpm'	System	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '15'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User entered 'breaths/min'	System	16 Nov 2020 15:41:42



**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '138'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User entered 'mmHg'	System	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:33
User entered '84'	Afifah Ayub (b) (4)	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50
User entered 'mmHg'	System	16 Nov 2020 15:41:42

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50

**US3212250**

**Folder: Unscheduled 13 Nov 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:49:32**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:18:50

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:49:32**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:26
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)' reason for change: New Information	Afifah Ayub (b) (4)	17 Sep 2020 17:01:08
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:05

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12



US3212250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of chest wall - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 11:45:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 11:45:55
Data point term sent to Coder	System	17 Sep 2020 17:02:27
User entered 'chest contusion'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User entered empty.	System	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Sep 2020 17:47:14
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55



US3212250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
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	23 Sep 2020 18:17:19
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	23 Sep 2020 18:17:19
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	23 Sep 2020 17:47:14
User entered '21 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Sep 2020 17:47:14
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User entered empty.	System	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	23 Sep 2020 18:17:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	17 Sep 2020 17:01:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User entered '0'	System	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12
User entered '0'	System	17 Sep 2020 17:01:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:12

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14

US3212250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Per DM CLR: Please verify if this pertains to INJECTION SITE PAIN. If yes, note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol 8.3.4. Please review if recorded event meets criteria. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:18:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in joint involving shoulder region - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 20:40:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 20:40:46
Data point term sent to Coder	System	16 Nov 2020 15:39:22
Coding entries removed.	Afifah Ayub (b) (4)	16 Nov 2020 15:38:36
User entered 'Left AC joint soreness' reason for change: Data Entry Error	Afifah Ayub (b) (4)	16 Nov 2020 15:38:36
Query 'Per DM CLR: Please verify if this pertains to INJECTION SITE PAIN. If yes, note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol 8.3.4. Please review if recorded event meets criteria. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' answered with 'ongoing, clearly meets criteria' (Site from DM).	Reagan Reed (b) (4)	05 Nov 2020 16:36:04
User opened query 'Per DM CLR: Please verify if this pertains to INJECTION SITE PAIN. If yes, note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol 8.3.4. Please review if recorded event meets criteria. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:53:40

US3212250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:50:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:50:44
Data point term sent to Coder	System	19 Oct 2020 16:48:55
User entered 'injection site soreness'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14



US3212250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '17 Sep 2020'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 16:48:21
User entered '15:00' reason for change: Data Entry Error	Afifah Ayub (b) (4)	19 Oct 2020 16:48:21
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 16:48:14
User entered empty.	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User entered '17 Sep 2020 15:00'	System	19 Oct 2020 16:48:21
User entered empty.	System	19 Oct 2020 16:48:14

US3212250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	(b) (4)	
	Heather Leary (b) (4)	13 Apr 2021 22:12:24
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Apr 2021 22:12:24
	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	08 Dec 2020 06:10:24
' (Site from DM).		
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	Anna Pena (b) (4)	25 Nov 2020 19:26:55
' answered with 'Pain is ongoing and intermittent in nature' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	25 Nov 2020 07:11:02
' (Site from DM).		
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14
	(b) (4)	

US3212250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	(b) (4) Heather Leary (b) (4)	13 Apr 2021 22:12:24
User entered '1 Jan 2021' reason for change: New Information	(b) (4) Heather Leary (b) (4)	13 Apr 2021 22:12:24
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	(b) (4) Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Signature has been broken.	System	13 Apr 2021 22:12:39
User entered '16:30' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Apr 2021 22:12:39
User opened query 'Data is required. Please provide.' (Site from System).	Heather Leary (b) (4)	13 Apr 2021 22:12:39
User signature succeeded.	System	13 Apr 2021 22:12:24
User entered empty.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User entered '1 Jan 2021 16:30'	System	13 Apr 2021 22:12:39
User entered empty.	System	19 Oct 2020 16:48:14



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	16 Nov 2020 15:38:47
User entered 'Related (RELATED)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

US3212250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:18:16
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Reagan Reed (b) (4)	18 Nov 2020 14:47:22
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	18 Nov 2020 14:47:17
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:09:40
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	16 Nov 2020 15:38:47
reason for change: Data Entry Error	(b) (4)	
User entered 'Related (RELATED)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0' reason for change: Data Entry Error	Anna Pena (b) (4)	25 Nov 2020 19:27:11
User entered '1'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '1' reason for change: Data Entry Error	Anna Pena (b) (4)	25 Nov 2020 19:27:11
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:49:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	(b) (4) Heather Leary (b) (4)	13 Apr 2021 22:12:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Heather Leary (b) (4)	13 Apr 2021 22:12:24
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Heather Leary (b) (4)	14 Jan 2021 20:42:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	16 Nov 2020 15:38:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User entered '0'	System	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14
User entered '0'	System	19 Oct 2020 16:48:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:14



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Shoulder bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 17:35:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 17:35:31
Data point term sent to Coder	System	18 Dec 2020 17:14:53
User entered 'Bursitis of left shoulder'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User entered empty.	System	18 Dec 2020 17:13:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:13:12
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:13:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:13:12
User entered '1 Jan 2021' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:13:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

US3212250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Apr 2021 22:13:24
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	13 Apr 2021 22:13:24
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Apr 2021 22:13:12
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:13:12
User entered '16:30' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Apr 2021 22:13:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User entered empty.	System	13 Apr 2021 22:13:24
User entered '1 Jan 2021 16:30'	System	13 Apr 2021 22:13:12
User entered empty.	System	18 Dec 2020 17:13:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Dec 2020 17:13:55
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

US3212250

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:41
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:13:55
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55



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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:13:55
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:13:55
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:13:55
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:49:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:13:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	13 Apr 2021 22:13:12
Data Entry Error	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User entered '0'	System	18 Dec 2020 19:27:41

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16
User entered 'I'	System	18 Dec 2020 17:13:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:16

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	14 Jan 2021 12:13:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Jan 2021 12:13:52
User closed query 'Per DM CLR: Please review AE and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.). Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 12:02:48
Data point term sent to Coder	System	13 Jan 2021 17:10:00
Query 'Per DM CLR: Please review AE and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.). Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Heather Leary (b) (4)	13 Jan 2021 17:09:18
Coding entries removed.	Heather Leary (b) (4)	13 Jan 2021 17:09:11
User entered 'OSTEOARTHRITIS OF LEFT SHOULDER' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Jan 2021 17:09:11
User opened query 'Per DM CLR: Please review AE and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, Gout, etc.). Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:54:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Shoulder arthritis - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 17:35:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 17:35:31
Data point term sent to Coder	System	18 Dec 2020 17:15:54

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Arthritis of left shoulder'	(b) (4), (b) (6) ou	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User entered empty.	System	18 Dec 2020 17:14:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:13:55
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:13:55
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	(b) (4) Heather Leary (b) (4)	13 Apr 2021 22:13:55
User entered '1 Jan 2021' reason for change: New Information	(b) (4) Heather Leary (b) (4)	13 Apr 2021 22:13:55
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User entered empty.	System	18 Dec 2020 17:14:57

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Dec 2020 17:14:57
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:55
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:55
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:14:57
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:55
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:14:57
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:55
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:14:57
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:27:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:27:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:27:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Dec 2020 17:14:57
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

US3212250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:49:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	(b) (4) Heather Leary (b) (4)	13 Apr 2021 22:13:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:13:55
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:14:57

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User entered '0'	System	18 Dec 2020 19:27:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20
User entered 'I'	System	18 Dec 2020 17:14:57



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:20

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff injury - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 17:35:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 17:35:25
Data point term sent to Coder	System	18 Dec 2020 17:15:54
User entered 'Left rotator cuff strain'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User entered empty.	System	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:14:29
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:14:29
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:14:29
User entered '1 Jan 2021' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:14:29
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User entered empty.	System	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:28:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:28:41
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:28:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Dec 2020 17:15:32
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:28:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:28:41
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:28:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:15:32
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:28:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:28:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:28:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:15:32
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:28:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:28:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:28:41
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:15:32
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:28:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 19:28:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	18 Dec 2020 19:28:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Dec 2020 17:15:32
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

US3212250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:49:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:14:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	13 Apr 2021 22:14:29
New Information	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User entered '0'	System	18 Dec 2020 19:28:41

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23
User entered 'I'	System	18 Dec 2020 17:15:32

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:23

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30

US3212250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 20:11:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 20:11:35
Data point term sent to Coder	System	08 Feb 2021 20:10:48
User entered 'Fall'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User entered empty.	System	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User entered empty.	System	08 Feb 2021 20:10:19

US3212250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:22:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:22:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:22:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 20:10:19
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

US3212250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

US3212250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

US3212250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:22:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:22:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:22:35
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:10:19
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

US3212250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:49:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:22:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:22:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:22:35
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:10:19
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Fractured right elbow'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User entered '0'	System	08 Feb 2021 20:10:19

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30
User entered 'I'	System	08 Feb 2021 20:10:19



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:30

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 20:12:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 20:12:36
Data point term sent to Coder	System	08 Feb 2021 20:11:49
User entered 'Fractured right elbow'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User entered empty.	System	08 Feb 2021 20:11:00

US3212250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:15:11
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:15:11
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:23:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:23:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:23:14
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:11:00
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

US3212250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:15:11
User entered '30 Mar 2021' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:15:11
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User entered empty.	System	08 Feb 2021 20:11:00

US3212250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:49:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:23:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:23:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:23:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 20:11:00
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:49:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:49:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:23:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:23:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:23:14
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:11:00
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:23:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:23:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:23:14
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:11:00
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 23:23:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 23:23:14
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Leary (b) (4)	09 Feb 2021 23:23:14
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:11:00
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

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**Folder: Adverse Events**

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

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Folder: Adverse Events

Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:15:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	13 Apr 2021 22:15:11
New Information	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

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**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User entered '0'	System	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34
User entered '1'	System	08 Feb 2021 20:11:00

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:34

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Folder: Adverse Events

Form: Adverse Events (8)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 12:57:37
Un-reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 12:57:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:31:32
User entered	System	16 Feb 2021 15:21:45
'USA-US115-2021-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	16 Feb 2021 15:21:45

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal fistulae, PT: Enterovesical fistula, LLT: Colovesical fistula - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 06:54:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 06:54:35
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	06 Apr 2021 23:32:22
Data point term sent to Coder	System	06 Apr 2021 19:12:47
Coding entries removed.	Laura Ngansop Djampou (b) (4)	06 Apr 2021 19:12:34
Signature has been broken.	Laura Ngansop Djampou (b) (4)	06 Apr 2021 19:12:34
User entered 'COLOVESCIAL FISTULA' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	06 Apr 2021 19:12:34
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal fistulae, PT: Colonic fistula, LLT: Colonic fistula - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 23:45:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 23:45:53
Data point term sent to Coder	System	12 Feb 2021 23:45:02
User entered 'colonic fistula'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '11 Feb 2021'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered empty.	[REDACTED] Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 23:44:03

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Apr 2021 22:05:48
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:05:48
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Apr 2021 22:05:48
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Apr 2021 22:04:48
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Please see AE log and con procedures, subject underwent partial colectomy 05APR2021' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 15:46:00
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	Heather Leary (b) (4)	13 Apr 2021 22:15:50
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).	(b) (4)	
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	13 Apr 2021 22:05:48
Signature has been broken.	System	
User entered '5 Apr 2021' reason for change: Data Entry Error	System	13 Apr 2021 22:05:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	System	13 Apr 2021 22:04:48
User signature succeeded.	Heather Leary (b) (4)	13 Apr 2021 22:04:48
	(b) (4)	
	Heather Leary (b) (4)	13 Apr 2021 22:04:48
	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 12:13:41
	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:57:21
Query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'end time only to be provided in the event that the AE began and ended within a 24 hour period. invalid query' (Site from Safety).	Reagan Reed (b) (4)	22 Feb 2021 15:29:19
	(b) (4)	
User opened query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:55:08
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 23:44:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '1'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered '11 Feb 2021'	[REDACTED] Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:49:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '12 Feb 2021'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	



**US3212250**

**Folder: Adverse Events**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered empty.	[REDACTED] Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

**US3212250**

**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:46:03
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' answered with 'updated' (Site from Safety).	Heather Leary (b) (4) (b) (4)	13 Apr 2021 15:34:23
Signature has been broken.	Heather Leary (b) (4) (b) (4)	13 Apr 2021 15:34:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	13 Apr 2021 15:34:02
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:14:24
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	06 Apr 2021 23:32:22
Signature has been broken.	Laura Ngansop Djampou (b) (4)	06 Apr 2021 19:11:51
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	06 Apr 2021 19:11:51
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	25 Apr 2021 17:56:22
User closed query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:08
Query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).	Heather Leary (b) (4) (b) (4)	22 Apr 2021 20:02:04
Signature has been broken.	Heather Leary (b) (4) (b) (4)	22 Apr 2021 20:01:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	22 Apr 2021 20:01:43
User opened query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:47:12
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:16
Signature has been broken.	Laura Ngansop Djampou (b) (4)	05 Apr 2021 19:03:55
User entered 'None (NONE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	05 Apr 2021 19:03:55
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:55:47
Query 'As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	22 Feb 2021 15:38:29
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	22 Feb 2021 15:30:47
User opened query 'As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:55:31



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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:03
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered '1'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:15:58
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Resolved with con procedure' (Site from Safety).	Heather Leary (b) (4) (b) (4)	14 Apr 2021 15:21:53
Signature has been broken.	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:05:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:05:48
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:14:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:57:01
Query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'shy of surgery this will remain open. subject has not confirmed is she is considering surgery at this time, Please do not leave queries open like this as the site will update when information is available.' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	22 Feb 2021 15:42:51
User opened query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:55:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	02 Apr 2021 21:27:10
User entered empty.	[REDACTED] Heather Leary (b) (4) (b) (4)	12 Feb 2021 23:44:03

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:18:15
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'done. medical records sent via email.' (Site from Safety).	Jagruiti Patel (b) (4) (b) (4)	14 Apr 2021 17:29:07
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:13:54
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:56:34
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 'per progress notes no indication that subject was tested for COVID 19.' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	22 Feb 2021 15:43:31

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Narrative](#)

Audit	User	Time (GMT)
User opened 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)	19 Feb 2021 20:55:57
User entered 'SUBJECT ADMITTED ON 2/11/21 FOR UTI AND SEPSIS DUE TO COLONIC FISTULA. DISCHARGED WITH ORAL COURSE OF ANTIBIOTICS 2/12/21.'	Heather Leary (b) (4)	12 Feb 2021 23:44:03



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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 23:44:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Feb 2021 23:44:03

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**Folder: Adverse Events**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Feb 2021 23:44:03

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 23:45:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 23:45:52
Data point term sent to Coder	System	12 Feb 2021 23:45:02
User entered 'urinary tract infection'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52



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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:20:33
User entered '7 Feb 2021'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Start time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User entered empty.	System	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '11 Feb 2021'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User entered empty.	System	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52



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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52



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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Heather Leary (b) (4)	12 Feb 2021 23:44:52



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Leary (b) (4)	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User entered '0'	System	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41
User entered '1'	System	12 Feb 2021 23:44:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:41

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52



US3212250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hand fracture, LLT: Fractured thumb - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 23:00:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 23:00:51
Data point term sent to Coder	System	17 Mar 2021 14:22:11
User entered 'Fractured Right Thumb'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

US3212250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User entered empty.	System	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:16:12
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:16:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:16:12
User entered '30 Mar 2021' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:16:12
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User entered empty.	System	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

US3212250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37



US3212250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

US3212250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:49:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:16:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	13 Apr 2021 22:16:12
Data Entry Error	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:21:37



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User entered '0'	System	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52
User entered 'I'	System	17 Mar 2021 14:21:37

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:52

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53

US3212250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fracture rib - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 22:59:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 22:59:52
Data point term sent to Coder	System	17 Mar 2021 14:23:12
User entered 'Fractured Right Rib'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User entered empty.	System	17 Mar 2021 14:22:27

US3212250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:16:43
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:16:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Folder: Adverse Events**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:16:43
User entered '30 Mar 2021' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:16:43
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User entered empty.	System	17 Mar 2021 14:22:27

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**Folder: Adverse Events**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27



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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Folder: Adverse Events**

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**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27



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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:16:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	13 Apr 2021 22:16:43
New Information	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:22:27

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**Folder: Adverse Events**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User entered '0'	System	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53
User entered 'I'	System	17 Mar 2021 14:22:27

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:53

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58



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Form: Adverse Events (12)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fracture rib - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 22:59:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 22:59:51
Data point term sent to Coder	System	17 Mar 2021 14:24:12
User entered 'Fractured Left Rib'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User entered empty.	System	17 Mar 2021 14:23:14

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:17:05
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:17:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14



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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:17:05
User entered '30 Mar 2021' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:17:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User entered empty.	System	17 Mar 2021 14:23:14

**US3212250**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14



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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Folder: Adverse Events**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:17:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	13 Apr 2021 22:17:05
New Information	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:14



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User entered '0'	System	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58
User entered '1'	System	17 Mar 2021 14:23:14

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:41:58

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03

US3212250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 14:24:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 14:24:44
Data point term sent to Coder	System	17 Mar 2021 14:24:12
User entered 'Worsening hypertension'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

US3212250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:49:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '04 Mar 2021'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User entered empty.	System	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:17:38
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:17:38
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:17:38
User entered '1 Apr 2021' reason for change: New Information	Heather Leary (b) (4)	13 Apr 2021 22:17:38
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User entered empty.	System	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

US3212250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:49:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Related (NOT RELATED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Applicable (NOT APPLICABLE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'None (NONE)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:49:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe (CM#12 METOPROLOL). Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:44:03
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:17:15
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe (CM#12 METOPROLOL). Please review and update this field.' answered with 'updated' (Site from DM).	Jagruti Patel (b) (4)	05 Apr 2021 14:01:04
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 14:00:49
User entered '0' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 14:00:49
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe (CM#12 METOPROLOL). Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:12:39
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '1'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

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Folder: Adverse Events

Form: Adverse Events (13)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	05 Apr 2021 14:17:15
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 14:00:49
User entered '1' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 14:00:49
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:49:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Signature has been broken.	Heather Leary (b) (4)	13 Apr 2021 22:17:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Leary (b) (4)	13 Apr 2021 22:17:38
Data Entry Error	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User entered '0'	System	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03
User entered 'I'	System	17 Mar 2021 14:23:55

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:03

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:18:55
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered	(b) (4)	
'USA-US115-2021-mRNA-1273-P301000013'	(b) (4), (b) (6)	14 Apr 2021 17:19:21



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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Since the event is a treatment procedure for a diagnosis which is already reported as a SAE, therefore kindly consider deleting the event as treatment procedures are not reportable.	(b) (4), (b) (6)	23 Apr 2021 15:16:05
' (Site from Safety). Query 'PV Query: Since the event is a treatment procedure for a diagnosis which is already reported as a SAE, therefore kindly consider deleting the event as treatment procedures are not reportable.	Heather Leary (b) (4)	22 Apr 2021 20:03:59
' answered with 'The treatment and underlying condition resulted in patient hospitalization and is hence an SAE' (Site from Safety). User opened query 'PV Query: Since the event is a treatment procedure for a diagnosis which is already reported as a SAE, therefore kindly consider deleting the event as treatment procedures are not reportable.	(b) (4), (b) (6)	22 Apr 2021 19:48:25
' (Site from Safety). User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal fistulae, PT: Enterovesical fistula, LLT: Colovesical fistula - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 20:20:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 20:20:44
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Data point term sent to Coder	System	14 Apr 2021 16:08:28
User entered 'COLOVESICULAR FISTULA (sigmoid colectomy surgery)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Apr 2021 16:08:00
Data point term sent to Coder	System	13 Apr 2021 22:10:55
User entered 'INPATIENT HOSPITALIZATION FOR SIGMOID COLECTOMY FOR COLOVESICULAR FISTULA'	Heather Leary (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered '5 Apr 2021'	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered empty.	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:38:38
Signature has been broken.	(b) (4)	
	Heather Leary (b) (4)	19 Apr 2021 15:13:05
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	19 Apr 2021 15:13:05
	(b) (4)	
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered 'No (N)'	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:38:38
User closed query 'Per CDM: Previous response noted 'dates provided are dates of hospitalization'. Please review/update to provide actual AE start/End dates and update as appropriate. If AE has 'Resolved' then update response for ' Outcome' accordingly else, clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:17:10
Query 'Per CDM: Previous response noted 'dates provided are dates of hospitalization'. Please review/update to provide actual AE start/End dates and update as appropriate. If AE has 'Resolved' then update response for ' Outcome' accordingly else, clarify. Thank you' answered with 'updated to ongoing per source' (Site from DM).	Heather Leary (b) (4) (b) (4)	19 Apr 2021 15:13:26
Signature has been broken.	Heather Leary (b) (4) (b) (4)	19 Apr 2021 15:13:05
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	19 Apr 2021 15:13:05
User opened query 'Per CDM: Previous response noted 'dates provided are dates of hospitalization'. Please review/update to provide actual AE start/End dates and update as appropriate. If AE has 'Resolved' then update response for ' Outcome' accordingly else, clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 10:56:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 10:53:30
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'dates provided are dates of hospitalization' (Site from System).	Heather Leary (b) (4) (b) (4)	14 Apr 2021 16:08:38
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	14 Apr 2021 16:08:00
User entered '8 Apr 2021'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

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EAB) (1725)

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**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered empty.	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 22:10:39

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
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	14 Apr 2021 15:19:20
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	System	14 Apr 2021 15:19:20
User opened query 'Data is required. Please complete.' (Site from System).	Heather Leary (b) (4)	14 Apr 2021 15:19:20
User entered empty.	(b) (4)	
	System	13 Apr 2021 22:10:39
	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered 'I'	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered '5 Apr 2021'	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered '8 Apr 2021'	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	13 Apr 2021 22:20:18
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		13 Apr 2021 22:20:18
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:20:18
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	13 Apr 2021 22:10:39
User entered 'Unknown (UNK)'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered empty.	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4)	
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:27:46
User closed query 'Data is required. Please complete.' (Site from System).	Heather Leary (b) (4)	14 Apr 2021 15:19:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	14 Apr 2021 15:19:20
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	System	14 Apr 2021 15:19:20
User opened query 'Data is required. Please complete.' (Site from System).	Heather Leary (b) (4)	14 Apr 2021 15:19:20
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:29:28
	System	13 Apr 2021 22:10:39
	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4)	
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 17:27:50
User closed query 'Data is required. Please complete.' (Site from System).	Heather Leary (b) (4)	14 Apr 2021 15:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	14 Apr 2021 15:19:20
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	System	14 Apr 2021 15:19:20
User opened query 'Data is required. Please complete.' (Site from System).	Heather Leary (b) (4)	14 Apr 2021 15:19:20
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 14:29:38
	System	13 Apr 2021 22:10:39
	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	04 May 2021 00:19:00
Query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'updated' (Site from Safety).	Heather Leary (b) (4)	30 Apr 2021 18:13:24
Signature has been broken.	Heather Leary (b) (4)	30 Apr 2021 18:13:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Heather Leary (b) (4)	30 Apr 2021 18:13:00
User opened query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 17:14:18
User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 19:13:24
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 15:19:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 15:19:20
User entered 'None (NONE)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Apr 2021 15:19:20
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 22:10:39
User entered empty.	Heather Leary (b) (4)	13 Apr 2021 22:10:39

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered '0'	Heather Leary (b) (4)	13 Apr 2021 22:10:39
	(b) (4)	

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered 'I'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 17:15:15
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Apr 2021 16:08:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Leary (b) (4)	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered empty.	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:10:39

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:49:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered 'She reports an inpatient admission and surgery of sigmoid colectomy for colovesical fistula on 04APRIL2021. She remained hospitalized for recovery until 08APRIL2021 after which she was transferred to inpatient rehab. Hospitalization occurred at HCA Clear Lake Regional Medical Center. Subject has several new medications but does not remember the names and dosages. Medical records have been requested and medication list will be updated accordingly after chart review.' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Apr 2021 22:11:38
User entered empty.	Heather Leary (b) (4)	13 Apr 2021 22:10:39



**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 22:10:39

**US3212250**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:49:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 22:10:39

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 15:49:32**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:26
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:02:11
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 Aug 2020 22:02:11
Data point term sent to Coder User entered 'Metoprolol'	System Afifah Ayub (b) (4) (b) (4)	19 Aug 2020 22:00:53 19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Hypertension'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '50'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:49:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:41:51
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	19 Aug 2020 21:59:51
User entered 'UN UNK 2000'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Mar 2021 13:44:40
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '4 Mar 2021' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Mar 2021 13:44:40
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User entered '1'	System	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User entered '1'	System	19 Aug 2020 21:59:51

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:56:52
User entered '804 (804)'	System	19 Aug 2020 21:59:51

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
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)	19 Aug 2020 22:02:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 22:02:11
Data point term sent to Coder	System	19 Aug 2020 22:00:52
User entered 'Multivitamin'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:48:02
	(b) (4), (b) (6)	07 Apr 2021 14:32:57
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	Heather Leary (b) (4)	06 Apr 2021 14:41:29
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'UPDATED' (Site from DM).	Heather Leary (b) (4)	06 Apr 2021 14:41:06
Signature has been broken.	Heather Leary (b) (4)	06 Apr 2021 14:41:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	06 Apr 2021 09:45:03
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User signature succeeded.	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'General Health'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '1'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'capsule (CAPSULE)'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:41:51
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	19 Aug 2020 22:00:29
User entered 'UN UNK 2010'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:49:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:29
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 22:00:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 22:00:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 22:00:29



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
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)	17 Oct 2020 09:56:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:56:21
Data point term sent to Coder	System	16 Oct 2020 17:01:48
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 17:00:55
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)	08 Oct 2020 21:41:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 21:41:36
Data point term sent to Coder	System	08 Oct 2020 14:36:55
User entered 'Influenza Vaccination'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:49:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Per DM CLR: Indication = IMMUNIZATION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:43:35
Query 'Per DM CLR: Indication = IMMUNIZATION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	24 Nov 2020 14:42:13
User opened query 'Per DM CLR: Indication = IMMUNIZATION. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:36:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	11 Nov 2020 16:09:59
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Immunization' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 17:00:55
User entered 'Vaccination'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 17:00:55
User entered '1'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:49:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	16 Oct 2020 17:01:11
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	16 Oct 2020 17:00:55
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 17:00:55
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:49:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 17:01:11
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	08 Oct 2020 14:36:42
User entered 'Vaccine' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:42
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	08 Oct 2020 14:36:29
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:49:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Intramuscular (INTRAMUSCULAR)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:05:56
User entered '7 Oct 2020'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:05:56
User entered '7 Oct 2020'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User entered empty.	System	08 Oct 2020 14:36:29



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User entered empty.	System	08 Oct 2020 14:36:29

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:04
User entered empty.	System	08 Oct 2020 14:36:29

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 20:18:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 20:18:57
Data point term sent to Coder	System	14 Jan 2021 20:18:07
Coding entries removed.	Heather Leary (b) (4)	14 Jan 2021 20:17:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 16:12:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 16:12:33
Data point term sent to Coder	System	11 Nov 2020 16:11:51
User entered 'Tylenol'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:49:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 09:38:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated per sub-investigator assessment' (Site from DM).	Heather Leary (b) (4)	14 Jan 2021 20:17:55
User entered 'left AC joint soreness' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 20:17:45
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:32:08
User entered 'Injection Site Soreness'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '500'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '04 Nov 2020'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query ' Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 09:38:18
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 20:36:57
Query ' Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Heather Leary (b) (4)	14 Jan 2021 20:18:02
User opened query ' Per DM CLR: Was this medication taken for solicited event?=YES. However, this condition is not within the 7 day post IP admin. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:32:17
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '30 Nov 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 20:36:57
User entered empty.	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:49:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 20:17:45
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User entered empty.	System	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User entered empty.	System	11 Nov 2020 16:11:40

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:05
User entered empty.	System	11 Nov 2020 16:11:40

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:55:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:55:42
Data point term sent to Coder	System	18 Dec 2020 17:08:44
User entered 'Tizanidine'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Left AC joint soreness'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '2'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once daily (QD)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:49:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:49:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '24 Nov 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	14 Jan 2021 20:37:19
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '30 Nov 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 20:37:19
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User entered '1'	System	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User entered '1'	System	18 Dec 2020 17:08:08

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:07
User entered '804 (804)'	System	18 Dec 2020 17:08:08

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:33
Data point term sent to Coder	System	18 Dec 2020 17:09:47
User entered 'Meloxicam'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Left AC joint soreness'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '15'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once daily (QD)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '24 Nov 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)' reason for change: New Information	Heather Leary (b) (4)	14 Jan 2021 20:37:38
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '30 Nov 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	14 Jan 2021 20:37:38
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User entered '1'	System	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User entered '1'	System	18 Dec 2020 17:08:57

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:09
User entered '804 (804)'	System	18 Dec 2020 17:08:57



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:39:43
Data point term sent to Coder	System	18 Dec 2020 17:10:48
User entered 'Methylprednisolone'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Bursitis of left shoulder'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '40'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Intra-articular'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:10:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 17:10:44
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:44
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 17:10:21
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User entered empty.	System	18 Dec 2020 17:10:21



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User entered empty.	System	18 Dec 2020 17:10:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:10
User entered empty.	System	18 Dec 2020 17:10:21

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:49:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:35:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:35:46
Data point term sent to Coder	System	18 Dec 2020 17:12:51
User entered 'Lidocaine 1%'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Bursitis of left shoulder'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '10'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mL (mL)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'intra-articular'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '03 Dec 2020'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User entered empty.	System	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User entered empty.	System	18 Dec 2020 17:12:21

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:16
User entered empty.	System	18 Dec 2020 17:12:21

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE NO. 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 08:52:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 08:52:44
Data point term sent to Coder	System	08 Feb 2021 20:12:51
User entered 'Tylenol 3 (codeine/acetaminophen)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:12:06

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:12:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 20:12:15
User entered 'Fractured Right Elbow' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:12:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:12:06
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:12:06

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '30/300'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:12:06

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'as needed (PRN)'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:12:06

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:12:06

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:49:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou	08 Feb 2021 20:12:06
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 20:12:06

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 20:12:06

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 20:12:06

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:53
Data point term sent to Coder	System	12 Feb 2021 23:46:03
User entered 'cefdinir'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'colonic fistula'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '300'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:49:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:49:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:49:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'twice daily (BID)'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:49:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:49:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '11 Feb 2021'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:49:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:45:47
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Feb 2021 23:45:47

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 23:45:47

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Feb 2021 23:45:47



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 23:47:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 23:47:52
Data point term sent to Coder	System	12 Feb 2021 23:47:04
User entered 'ciprofloxacin'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'urinary tract infection'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '500'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once daily (QD)'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:49:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:46:20



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:46:20

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:49:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	17 Mar 2021 14:18:09
User entered '7 Feb 2021'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:49:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 23:46:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Feb 2021 23:46:25
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	12 Feb 2021 23:46:25
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 23:46:20
User entered empty.	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '10 Feb 2021'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Heather Leary (b) (4)	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User entered '1'	System	12 Feb 2021 23:46:20



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User entered '1'	System	12 Feb 2021 23:46:20

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:57:18
User entered '804 (804)'	System	12 Feb 2021 23:46:20

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	02 Apr 2021 11:02:24
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #1 METOPROLOL. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate, or provide clarification. ' (Site from DM).	Coder Import (b) (4)	29 Mar 2021 13:46:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 13:46:35
Data point term sent to Coder	System	29 Mar 2021 13:45:13
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #1 METOPROLOL. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate, or provide clarification. ' answered with 'updated ' (Site from DM).	Reagan Reed (b) (4)	29 Mar 2021 13:45:04
Coding entries removed.	Reagan Reed (b) (4)	29 Mar 2021 13:44:57
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #1 METOPROLOL. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate, or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 03:11:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 14:20:44
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Mar 2021 14:20:44
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	17 Mar 2021 14:20:09
User entered 'Metoprolol'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Worsening HYPERTENSION' reason for change: Data Entry Error	Reagan Reed (b) (4)	29 Mar 2021 13:44:57
	(b) (4)	
User entered 'Hypertension'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '75'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'mg (mg)'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	



US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'once daily (QD)'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Oral (ORAL)'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

US3212250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:49:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '04 Mar 2021'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '0'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	



**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'No (N)'	Laura Ngansop Djampou	17 Mar 2021 14:19:10
	(b) (4)	

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 14:19:10

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 14:19:10

**US3212250**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:49:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 14:19:10

**US3212250**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 15:49:32**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:28:26
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:12:57
User entered 'No (N)'	Afifah Ayub (b) (4)	19 Aug 2020 22:00:46

US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:49:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:48
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:18

US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:49:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:48
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'X-ray of right upper extremity'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:18



**US3212250**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:48
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Adverse Event (AE)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:18

US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:49:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:48
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:18

US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:49:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '07 Feb 2021'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:43

**US3212250**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'CT Scan of head'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:43

**US3212250**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'Adverse Event (AE)'	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:43

US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:49:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:59
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered empty.	Laura Ngansop Djampou (b) (4)	08 Feb 2021 20:13:43

US3212250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:49:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered '5 Apr 2021'	Heather Leary (b) (4)	13 Apr 2021 22:02:37
	(b) (4)	

**US3212250**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered 'sigmoid colectomy'	Heather Leary (b) (4)	13 Apr 2021 22:02:37
	(b) (4)	



**US3212250**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
	(b) (4)	
User entered 'Adverse Event (AE)'	Heather Leary (b) (4)	13 Apr 2021 22:02:37
	(b) (4)	

**US3212250**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:49:32**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4) (b) (4)	16 Apr 2021 19:13:24
User entered empty.	Heather Leary (b) (4) (b) (4)	13 Apr 2021 22:02:37

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '16/Feb/2021 10:22'	System	16 Feb 2021 15:22:27

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:49:32

**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.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '16/Feb/2021 10:31'	System	16 Feb 2021 15:32:01

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:49:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:37:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 15:32:01

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered '23/Feb/2021 07:58'	System	23 Feb 2021 12:58:21

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:49:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:37:40
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 12:58:21

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45



US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:16
User entered '06/Apr/2021 06:02'	System	06 Apr 2021 13:02:09

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:49:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:37:40
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:53:16
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 13:02:09

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:48:02
User entered '07/Apr/2021 08:37'	System	07 Apr 2021 12:37:49

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:49:32

**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.	Vicki Miller (b) (4)	08 Apr 2021 18:48:02
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:37:54
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 12:37:49

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
User entered '14/Apr/2021 13:19'	(b) (4) System	14 Apr 2021 17:19:42



US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:49:32

**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.	Insiya Valika (b) (4)	16 Apr 2021 19:13:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:19:46
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 17:19:42

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:38:38
User entered '20/Apr/2021 08:19'	(b) (4) System	20 Apr 2021 13:20:00

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:49:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 15:59:43
User signature succeeded.	Insiya Valika (b) (4)	20 Apr 2021 18:38:38
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 13:20:00



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	25 Apr 2021 17:56:22
User entered '23/Apr/2021 11:59'	(b) (4) System	23 Apr 2021 15:59:59

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:49:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:15:09
User signature succeeded.	Insiya Valika (b) (4)	25 Apr 2021 17:56:22
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 15:59:59

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:22:05
User entered 'USA-US115-2021-MRNA-1273-P301000013'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
	(b) (4), (b) (6)	25 Feb 2021 17:33:35
User closed query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:34
User closed query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:33:32
User closed query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	
Query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' answered with 'per investigator only Colonic fistula reported at this time' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:58:07
Query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'request medical records. still pending. we will update the appropriate route of communication if medical records are obtained, do not leave open queries that only age and cause issue for site query metrics. ' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:57:41
Query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' answered with 'The root cause is Colonic Fistula - no second and third SAE needed' (Site from Safety).	Reagan Reed (b) (4)	24 Feb 2021 16:56:25

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:49:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Please assess whether UTI meets criteria for serious reporting as the subject was "hospitalized for UTI and sepsis due to colonic fistula." ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:29
User opened query 'Please assess whether sepsis meets criteria for separate AE/SAE reporting' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:54:13
User opened query 'Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 20:53:57
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Yes (Y)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'No (N)'	System	16 Feb 2021 15:21:45



**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Vicki'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'Miller'	System	16 Feb 2021 15:21:45

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	02 Apr 2021 21:27:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 15:24:44
User entered 'US'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:49:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 19:15:23
User entered '8'	System	23 Apr 2021 15:59:59
User entered '7'	System	20 Apr 2021 13:20:00
User entered '6'	System	14 Apr 2021 17:19:42
User entered '5'	System	07 Apr 2021 12:37:49
User entered '4'	System	06 Apr 2021 13:02:09
User entered '3'	System	23 Feb 2021 12:58:21
User entered '2'	System	16 Feb 2021 15:32:01
User entered '1'	System	16 Feb 2021 15:22:27

**US3212250**

**Folder: SAE USA-US115-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (9)**

**Generated On: 09 Jun 2021 15:49:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	01 May 2021 18:40:47
User entered '30/Apr/2021 12:15'	(b) (4) System	30 Apr 2021 19:15:23

US3212250

Folder: SAE USA-US115-2021-MRNA-1273-P301000013

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:49:32

**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.	Insiya Valika (b) (4)	01 May 2021 18:40:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:15:23